

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

NINA M. COOK, on behalf of herself  
and all others similarly situated,

Plaintiff,

v.

ABBVIE INC., ALLERGAN, INC.,  
ALLERGAN SALES, LLC, ALLERGAN USA,  
INC., FOREST LABORATORIES, INC.,  
FOREST LABORATORIES HOLDINGS,  
LTD., FOREST LABORATORIES  
IRELAND, LTD., and FOREST  
LABORATORIES, LLC,

Defendants.

Civil Action No. \_\_\_\_\_

**CLASS ACTION COMPLAINT**

**DEMAND FOR JURY TRIAL**

Plaintiff Nina M. Cook (“Plaintiff”), on behalf of herself and all others similarly situated, brings this Class Action Complaint against AbbVie, Inc. (“AbbVie”); Allergan, Inc., Allergan Sales, LLC, and Allergan USA, Inc. (collectively, “Allergan”); and Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Forest Laboratories, LLC, and Forest Laboratories Ireland Ltd. (collectively, “Forest”) (together with AbbVie and Allergan, “Defendants”) for Defendants’ violations of federal and state antitrust, consumer protection and unjust enrichment laws concerning the pharmaceutical drug Bystolic® (nebivolol hydrochloride) (“Bystolic”). Based upon the investigation of counsel, information and belief, and personal knowledge as to the allegations contained in paragraph 16, Plaintiff alleges as follows:

## I. INTRODUCTION

1. This is a civil antitrust action seeking treble damages and declaratory and injunctive relief brought under state antitrust, consumer protection and unjust enrichment law, and federal antitrust law, concerning Defendants' unlawful exclusion of generic substitutes for the branded drug Bystolic, which contains the active pharmaceutical ingredient nebivolol hydrochloride or nebivolol HCl. Bystolic is an important cardiovascular prescription drug used to treat high blood pressure. It is commonly referred to as a "beta blocker" or a beta-adrenergic blocking agent that reduces blood pressure. Beta-blockers block hormone epinephrine (adrenaline) and cause the heart to beat more slowly with less force, thereby lowering blood pressure.

2. Defendant Forest and its successors-in-interest manufacture, market and sell the branded version of Bystolic, which is a "blockbuster" prescription drug with annual U.S. sales exceeding \$1billion.<sup>1</sup> Potential new generic market entrants filed Abbreviated New Drug Applications ("ANDA") with the United States Food and Drug Administration (the "FDA") to manufacture, market and sell generic versions of Bystolic on December 17, 2011.<sup>2</sup> Despite these ANDAs filed nearly nine years ago, no generic competitor has or will enter the market until September 17, 2021.

3. Generic prescription drugs are typically less expensive than their branded counterparts, and perform 99.8% the same as the branded product in order to obtain FDA

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<sup>1</sup> Glenmark Pharmaceuticals receives ANDA approval for Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg, <https://www.glenmarkpharma.com/sites/default/files/Glenmark-receives-ANDA-approval-for-Nebivolol-Tablets%2C2.5-mg%2C5-mg%2C10-mg-and-20-mg.pdf>, May 29, 2017.

<sup>2</sup> *See, e.g.*, 11/27/2015 Letter from Food and Drug Administration ("FDA") to Watson, [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2015/203683Orig1s000Ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203683Orig1s000Ltr.pdf).

“bioequivalence” or “AB rated” status to enter the U.S. market. Access to less expensive generic prescription drugs is extremely important to society as they cause consumers and the health industry to save billions of dollars in prescription drug expenditures.<sup>3</sup> Notably, generic drugs typically cost 50% less than the branded product and capture 80% or more market share of the branded product within the first six to nine months upon entry. This rapid erosion is the result of generic substitution laws which generally require pharmacists to dispense the AB-rated generic product when available. The loss of market share causes the branded company of a “blockbuster” drug to lose millions of dollars in sales each day.

4. To avoid or delay these market realities, Defendant Forest entered into a series of unlawful reverse-payment agreements with potential generic competitors, including Hetero,<sup>4</sup> Torrent,<sup>5</sup> Alkem,<sup>6</sup> Indchemie,<sup>7</sup> Glenmark,<sup>8</sup> Amerigen<sup>9</sup> and Watson<sup>10</sup> (collectively, the “Generic Competitors”). From October 2012 through November 2013, Forest entered agreements with the generics to: (i) not compete with Forest or enter the market prior to September 17, 2021, unless another generic competitor entered the market earlier; and in exchange (ii) upon information and belief, provide consideration to the generics, through “side-deals,” and cash

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<sup>3</sup> *Generic Drugs Undergo Rigorous FDA Scrutiny*, U.S. Food & Drug Admin. (Oct. 8, 2014), <https://www.fda.gov/consumers/consumer-updates/generic-drugs-undergo-rigorous-fda-scrutiny>.

<sup>4</sup> Hetero USA, Inc. and Hetero Labs Ltd. (collectively, “Hetero”).

<sup>5</sup> Torrent Pharmaceuticals Ltd., and Torrent Pharma, Inc. (collectively “Torrent”).

<sup>6</sup> Alkem Laboratories Ltd. (“Alkem”).

<sup>7</sup> Indchemie Health Specialties Private Ltd. (“Indchemie”).

<sup>8</sup> Glenmark Generics Inc., USA, Glenmark Generics Ltd., and Glenmark Pharmaceuticals S.A. (collectively “Glenmark”).

<sup>9</sup> Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals, Ltd. (collectively, “Amerigen”).

<sup>10</sup> Watson Pharma, Inc. and Watson Pharmaceuticals, Inc. (“Watson”).

payments. As corporate successors-in-interest to one or more of the Defendants, Allergan and then AbbVie have perpetuated this illegal conduct<sup>11</sup> in the market for nebivolol HCl, all at the expense of consumers and health insurers.

5. Beginning on December 17, 2011,<sup>12</sup> Forest filed patent infringement actions against the generic companies that Filed ANDA applications accusing them of allegedly infringing U.S. Patent No. 6,545,040 (the “040 Patent”), which Forest successfully submitted for listing in the FDA Orange Book by certifying that the patent covered Bystolic. These suits, filed in mid-March 2012, automatically triggered 30-month stays under the Hatch-Waxman Act. 21 U.S.C. § 355(j)(5)(B)(iii). This prevented the FDA from granting final approval to any of the Generic Competitors to launch a generic product before June 18, 2015, absent an earlier favorable decision for the Generic Competitors or a dismissal of the actions.

6. Between March 2012 through November 2013, while the stays were in effect, the Generic Competitors fought the patent infringement suits and prepared to bring their generic Bystolic to market to compete with Forest’s branded Bystolic. At least six of the seven Generic Competitors would have been ready to launch well before September 17, 2021, as each had final FDA approval to enter the market.

7. The ‘040 Patent litigation would likely have concluded by mid-2015, including any appeals, in favor of the generic because the ‘040 Patent was weak. The Generic

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<sup>11</sup> *FTC v. Actavis*, 570 U.S. 136 (2013).

<sup>12</sup> *See, e.g.*, 11/27/2015 Letter from FDA to Watson, [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2015/203683Orig1s000Ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203683Orig1s000Ltr.pdf); 5/27/2017 Letter from FDA to Glenmark, [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2017/203821Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/203821Orig1s000ltr.pdf); 6/24/2015 Letter from FDA to Alkem, [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2015/203741Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203741Orig1s000ltr.pdf).

Competitors would have won and launched by the later of: (i) June 2015, which was the expiry of the only other patent that Forest contended covered Bystolic, U.S. Patent No. 5,759,580 (the “580 Patent”), or (i) the date their ANDAs were finally approved. Rather than risk facing competition from the Generic Competitors as early as June 2015 and the subsequent reduction in Bystolic brand sales and revenues, Forest entered into a prototypical “reverse-payment agreement” with the generics by sharing monopoly profits with them to induce them to stay out of the market until September 21, 2021. The result: the pharmaceutical companies won and health insurers and consumers, the intended victims of the anticompetitive scheme, were the biggest financial losers.

8. On February 18, 2014 Actavis PLC and Forest announced an equity and cash merger.<sup>13</sup> Forest’s outside lawyers at Weil, Gotshal & Manges LLP conducted due diligence and reviewed Forest’s documents as part of their “work on the Actavis merger agreement.”<sup>14</sup> On March 4, 2014, Forest’s outside lawyers identified the existence of “side deal” reverse-payment settlements with the generics noting that “[b]efore we engage in any discussions with the FTC . . . we think it would be prudent for us to review all of the Bystolic settlement and licensing agreements *as well as the side agreements with those generic companies*.”<sup>15</sup> The email exchange provided the following details:

We entered into settlement agreements with the following defendants:

- 1) Hetero
- 2) Torrent
- 3) Alkem

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<sup>13</sup> See Actavis to Acquire Forest Laboratories, Inc. for ~\$25 Billion in an Equity and Cash Transaction, <https://www.businesswire.com/news/home/20140218005877/en/Actavis-Acquire-Forest-Laboratories-25-Billion-Equity>.

<sup>14</sup> *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-44 at 332).

<sup>15</sup> *Id.* (emphasis added).

- 4) Indchemie
- 5) Glenmark
- 6) Amerigen
- 7) Actavis [Watson's successor]

***All had side-deals*** (one was struck with Alkem, which is a related company with Indchemie).<sup>16</sup>

9. Forest's Agreement and Plan of Merger with Actavis PLC (the "Merger Agreement"), dated February 17, 2014 disclosed "material contracts," which are defined to include "any Contract involving the settlement of any action or threatened action (or series of related actions) (A) which will (x) involve payments after the date hereof of consideration in excess of \$15,000,000 or (y) impose monitoring or reporting obligations to any other Person outside the ordinary course of business or (B) with respect to which material conditions precedent to the settlement have not been satisfied."<sup>17</sup>

10. Forest listed each of the side-deals as a "material contract" "in connection with the settlement of BYSTOLIC patent dispute" because it was a "Contract involving the settlement of any action or threatened action (or series of related actions) (A) which will (x) involve payments after the date hereof of consideration in excess of \$15,000,000 or (y) impose monitoring or reporting obligations to any other Person outside the ordinary course of business or (B) with respect to which material conditions precedent to the settlement have not been satisfied." A succinct summary of the relevant provisions follows:

**Hetero**: "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and Hetero USA Inc. and Hetero Labs Ltd. dated October 24, 2012 . . . together with the FINAL TERM SHEET between Hetero Drugs

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<sup>16</sup> *Id.* (emphasis added).

<sup>17</sup> *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22 at 69).

Ltd. and Forest Laboratories Ireland Ltd. dated October 5, 2012, in connection with the settlement of BYSTOLIC patent dispute.”<sup>18</sup>

**Torrent:** “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. dated November 21, 2012 . . . together with the PATENT ASSIGNMENT AGREEMENT between Torrent Pharmaceuticals Ltd and Forest Laboratories Holdings Ltd. dated November 21, 2012, in connection with the settlement of BYSTOLIC patent dispute.”<sup>19</sup>

**Alkem/Indchemie:** “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Alkem Laboratories Ltd. dated November 27, 2012 . . . together with the TERM SHEET between Alkem Laboratories Ltd., Indchemie Health Specialties Private Ltd., and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute. AMENDMENT NO. 1 TO SETTLEMENT AGREEMENT was executed on January 9, 2013” and “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and Indchemie Health Specialties Private Ltd. dated November 27, 2012 . . . together with the TERM SHEET between Alkem Laboratories Ltd, Indchemie Health Specialties Private Ltd, and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute.”<sup>20</sup>

**Glenmark:** “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and Glenmark Generics Inc., USA and Glenmark

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<sup>18</sup> *Id.* at 179.

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

Generics Ltd. dated December 21, 2012 . . . together with the COLLABORATION AND OPTION AGREEMENT between Glenmark Pharmaceuticals S.A. and Forest Laboratories Holdings Ltd. dated December 21, 2012, in connection with the settlement of BYSTOLIC patent dispute.”<sup>21</sup>

**Amerigen:** “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013 . . . together with the BINDING TERM SHEET COLLABORATION AGREEMENT between Forest Laboratories, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013, in connection with the settlement of BYSTOLIC patent dispute.”<sup>22</sup>

**Watson:** “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Watson Pharma, Inc., and Actavis, Inc. dated November 6, 2013 . . . together with (a) the LETTER from Forest Laboratories, Inc. to Moksha8, Inc. dated November 1, 2013 and (b) TERMINATION AND RELEASE AGREEMENT between Actavis, Inc. and Moksha8, Inc. dated November 4, 2013, in connection with the settlement of BYSTOLIC patent dispute.”<sup>23</sup>

11. As Forest publicly acknowledged, the side-deals were entered into as part and parcel of Forest’s patent settlement agreements with the Generic Competitors in the Bystolic patent litigation.

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<sup>21</sup> *Id.*

<sup>22</sup> *Id.* at 180.

<sup>23</sup> *Id.*



12. In addition to the consideration Forest provided each Generic Competitor in the form of a side-deal, Forest “agreed to reimburse certain of the Settling Defendants’ legal costs in connection with the patent litigation.”<sup>24</sup>

13. Forest also disclosed that its settlement agreements with the Generic Competitors “provide[d] a license to each of the Settling Defendants that will permit them to launch their respective generic versions of Bystolic as of the date that is the later of (a) three calendar months prior to the expiration of the ’040 patent, including any extensions and/or pediatric exclusivities or (b) the date that each Settling Defendant receives final FDA approval of its ANDA, **or earlier in certain circumstances**.”<sup>25</sup> The bolded language typically refers to what is known as a “contingent launch provision” (“CLP”), or an “acceleration clause.” CLPs ensure a settling generic that it will not be competitively disadvantaged should a later settling generic negotiate an earlier licensed entry date or otherwise come to market earlier: pursuant to the CLPs, the entry date may be “accelerated” permitting the settling generic to enter the market at the same time as any of its competitors. CLPs ensure settling generic ANDA filers that, if any other ANDA filer somehow makes it to market before the agreed-upon licensed entry date that ANDA filer’s licensed entry date would be accelerated so that it could launch at the same time.

14. When CLPs are used, they generally operate the same way in each ANDA filer’s settlement agreement. Under a CLP, the first-filing ANDA filer (or, as here, filers) obtains protection from other first filers by agreeing to delay the launch of their generic products from the date of settlement until a date certain (here, exactly three months before the expiration of

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<sup>24</sup> <https://www.sec.gov/Archives/edgar/containers/fix010/38074/000003807413000024/R17.htm>.

<sup>25</sup> *Id.* (emphasis added).

the '040 Patent),<sup>26</sup> but *if and only if* all other first-filer generic companies follow suit. By brokering the agreements, Forest ensured that, without regard to the strength of the Generic Competitors' challenges to the '040 Patent, Bystolic would have no generic competitors and Forest would maintain patent-generated monopoly profits until at least September 17, 2021, and none of its generic competitors would come to market earlier.

15. As a direct and proximate result of Defendants' conduct, Plaintiff and other class members have been injured in their business and property because they would have been able to purchase less expensive generic Bystolic instead of branded Bystolic at artificially inflated prices.

## II. PARTIES

16. Plaintiff Nina M. Cook ("Plaintiff") is an individual residing in West Virginia. Plaintiff purchased and paid for Bystolic, other than for resale, in the state of West Virginia during the Class Period. Absent the unlawful conduct alleged herein, Plaintiff would have purchased less expensive generic alternatives rather than branded Bystolic. During the Class Period, Plaintiff paid more than she would have absent Defendants' unlawful anticompetitive scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful conduct alleged herein. Plaintiff intends to purchase Bystolic in the future and will be injured if injunctive relief is not granted.

17. Defendant Forest Laboratories, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 909 Third Avenue, New York, New York 10022.

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<sup>26</sup> *Id.*

18. Defendant Forest Laboratories Ireland, Ltd. is an Irish Corporation with a place of business at Clonsaugh Industrial Estate, Dublin 17, Ireland.

19. Defendant Forest Laboratories Holdings, Ltd. is a Bermudian corporation having a principal place of business at 18 Parliament Street, Hamilton HM 11, Bermuda. In or around February 2006, Defendant Forest Laboratories Ireland, Ltd. changed its name to Forest Laboratories Holdings, Ltd. and changed its residence from Ireland to Bermuda.<sup>27</sup>

20. Defendant Forest Laboratories, LLC is a company organized and existing under the laws of Delaware, with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. On July 1, 2014, in a series of transactions, Forest Laboratories, Inc. became a limited liability company named Forest Laboratories, LLC. On July 1, 2014, Actavis PLC (“Actavis”) acquired Defendant Forest. On May 17, 2015 Actavis acquired Defendant Allergan, Inc. but maintained the name Allergan for its ongoing operations. Subsequently, on January 1, 2018, Forest Laboratories, LLC was merged with and into Defendant Allergan Sales, LLC, a Delaware limited liability company. As a result of these corporate consolidations, the Forest Defendants are predecessors in interest to Allergan Sales, LLC.

21. Defendant Allergan Sales, LLC is a company organized and existing under the laws of Delaware, with its principal place of business at 5 Giralda Farms, Madison, New Jersey 07940.

22. Defendant Allergan, Inc. is a Delaware corporation with its principal place of business located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

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<sup>27</sup> See, e.g., Notice and Stipulation of Name Change, *Forest Laboratories, et al. v. Ivax Pharmaceuticals, Inc., et al*, 03-cv-00891 (D. Del. Feb. 8, 2006) (ECF No. 536).

23. Defendant Allergan USA, Inc. is a Delaware corporation with its principal place of business at 5 Giralda Farms, Madison, New Jersey 07940.

24. Allergan, through its merger with Forest, assumed responsibility for performance of the challenged provisions in the agreements, continued to perform those provisions, and benefited from making indirect sales of Bystolic to Plaintiff and members of the proposed Class at the supracompetitive prices made possible by the delay those challenged provisions produced.<sup>28</sup>

25. On information and belief, Forest assigned the reverse-payment agreements to Allergan, and Allergan never withdrew from them.

26. On information and belief, Allergan joined the ongoing unlawful course of conduct – and joined the unlawful reverse-payment agreements – with respect to the suppression of generic competition for Bystolic. Allergan did not withdraw from those conspiracies and instead continued to participate in them.

27. Defendant AbbVie, Inc. is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is the corporate successor to Allergan and Forest, having completed its purchase of Allergan on May 8, 2020.

28. Defendant AbbVie, through its merger with Allergan, assumed responsibility for performance of the challenged provisions in the agreements, continued to perform those provisions, and benefited from making indirect sales of Bystolic to Plaintiff and members of the

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<sup>28</sup> See, e.g., Bystolic label, available at <https://www.dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=8b8ad213-1dc8-454e-a524-075685c0e1a8&type=display> (listing Allergan USA Inc. as the distributor of Bystolic).

proposed Class at the supracompetitive prices made possible by the delay those challenged provisions produced.

29. On information and belief, Allergan assigned the reverse-payment agreements to AbbVie, and AbbVie never withdrew from them.

30. On information and belief, AbbVie joined the ongoing unlawful course of conduct – and joined the unlawful reverse-payment agreements – with respect to the suppression of generic competition for Bystolic. AbbVie did not withdraw from those conspiracies and instead continued to participate in them.

31. Although not named as a Defendant, Watson Pharma, Inc. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Watson Pharma, Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

32. Although not named as a Defendant, Watson Pharmaceuticals, Inc. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Watson Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Nevada, having places of business at 311 Bonnie Circle, Corona, California 92880 and 360 Mount Kemble Avenue, Morristown, New Jersey 07962, and its corporate headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

33. Although not named as a Defendant, Torrent Pharmaceuticals Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Torrent Pharmaceuticals Ltd. is an Indian corporation having a principal place of business at Off. Ashram Road, Ahmedabad - 380 009, Gujarat, India.

34. Although not named as a Defendant, Torrent Pharma Inc. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Torrent Pharma Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 5380 Holiday Terrace, Suite 40, Kalamazoo, Michigan 49009. On information and belief, Torrent Pharma Inc. is a wholly-owned subsidiary of Torrent Pharmaceuticals Ltd. On information and belief, Torrent Pharma Inc. acts as the agent of Torrent Pharmaceuticals Ltd.

35. Although not named as a Defendant, Amerigen Pharmaceuticals Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Amerigen Pharmaceuticals Ltd. is a Chinese company having places of business at 197 State Route 18S, Suite 306N, East Brunswick, New Jersey 08816 and No. 58, Qunxing Yi Road, Suzhou Industrial Park, PRC, 215006.

36. Although not named as a Defendant, Amerigen Pharmaceuticals Inc. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Amerigen Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 197 State Route 18S, Suite 306N, East Brunswick, New Jersey 08816. On information and belief, Amerigen Pharmaceuticals Inc. is a wholly-owned subsidiary of Amerigen Pharmaceuticals Ltd. On information and belief, Amerigen Pharmaceuticals Inc. acts as the agent of Amerigen Pharmaceuticals Ltd.

37. Although not named as a Defendant, Glenmark Generics Inc., USA was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Glenmark Generics Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. Glenmark Generics Inc. is the same entity as Glenmark Generics Inc., USA. To the

extent Glenmark Generics Inc. is an entity separate and apart from Glenmark Generics Inc., USA, any allegations in this Complaint relating to Glenmark Generics Inc., USA shall apply equally to Glenmark Generics Inc.

38. Although not named as a Defendant, Glenmark Generics Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Glenmark Generics Ltd. is an Indian company having a place of business at Glenmark House, HDO-Corporate Building, Wing -A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, India.

39. Although not named as a Defendant, Defendant Glenmark Pharmaceuticals Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Glenmark Pharmaceuticals Ltd. is an Indian corporation having a principal place of business at Glenmark House, HDO-Corporate Building, Wing -A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, India. On information and belief Glenmark Generics Inc., USA and Glenmark Generics Ltd. are wholly-owned subsidiaries of Glenmark Pharmaceuticals Ltd. On information and belief, Glenmark Generics Inc., USA is the North American division of Glenmark Generics Ltd. On information and belief, Glenmark Generics Inc., USA, Glenmark Generics Ltd., and Glenmark Pharmaceuticals Ltd. have officers and directors in common. On information and belief, Glenmark Generics Inc., USA acts as the agent of Glenmark Generics Ltd. and Glenmark Pharmaceuticals Ltd.

40. Although not named as a Defendant, Hetero Labs Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Hetero Labs Ltd. is an Indian corporation having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estate, Sanathnagar Hyderabad 500018 Andhra Pradesh, India.

41. Although not named as a Defendant, Hetero USA Inc. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Hetero USA Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1031 Centennial Avenue, Piscataway, New Jersey 08854. On information and belief, Hetero USA Inc. is a wholly-owned subsidiary of Hetero Labs Ltd. On information and belief, Hetero USA Inc. acts as the agent of Hetero Labs Ltd.

42. Although not named as a Defendant, Indchemie Health Specialties Private Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Indchemie Health Specialties Private Ltd. is an Indian company having a place of business at 510, Shah & Nahar Industrila Estate, Dr. E. Moses Road, Worli-Mumbai 400018, India.

43. Although not named as a Defendant, Alkem Laboratories Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Alkem Laboratories Ltd. is an Indian company having a place of business at Alkem House, Devashish, Senapati Bapat Marg, Lower Parel (West), Mumbai 400013, Maharashtra, India.

44. All of the Defendants' and unnamed (as defendants) co-conspirators' actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by the Defendants' and unnamed co-conspirators' various officers, agents, employees, or other representatives while actively engaged in the management of the Defendants' and unnamed co-conspirators' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of the Defendants and unnamed co-conspirators.



### III. JURISDICTION AND VENUE

45. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds \$5,000,000, exclusive of interest and costs, there are more than one hundred Class members, and at least one member of the putative Class is a citizen of a state different from that of one of the Defendants. This Court also has jurisdiction under Section 16 of the Clayton Act, 15 U.S.C. § 26, and Sections 1 and 2 of the Sherman Act 15 U.S.C. §§ 1 and 2.

46. Venue is appropriate within this district under 28 U.S.C. §1391 and Section 12 of the Clayton Act 15 U.S.C. § 22 because, at all relevant times, Defendants transacted business within this district, and the interstate trade and commerce described hereinafter is carried out, in substantial part, in this district. Further, Defendants and/or their agents may be found in this district. Upon information and belief, the anticompetitive agreement emanated from Forest's New York headquarters.

47. Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

48. During the class period, Forest manufactured, sold and shipped Bystolic in a continuous and uninterrupted flow of interstate commerce. Defendants' anticompetitive conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

49. During the class period, each Defendant, or one or more of its affiliates, used the instrumentalities of interstate commerce to join or effectuate their scheme.

50. This Court has personal jurisdiction over each Defendant, because each Defendant has – throughout the United States and including in this District – transacted

business, maintained substantial contacts, and/or committed overt acts in furtherance of its illegal scheme and conspiracy. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

51. This Court has personal jurisdiction over each Defendant under 15 U.S.C. § 22 because each transacts business in this District. Personal jurisdiction lies under Fed. R. Civ. P. 4(k)(2) over the foreign domiciliary defendants.

#### IV. CLASS ACTION ALLEGATIONS

52. Plaintiff brings this action on behalf of herself and, under Federal Rule of Civil Procedure 23(a), (b)(2) and (b)(3), as a representative of a class of End Payors (the “Class”) defined as follows:

All persons and entities in the United States and its territories that indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Bystolic in any form, other than for resale, from June 2, 2015 through and until the anticompetitive effects of Defendants’ unlawful conduct cease (the “Class Period”).

53. The following persons and entities are excluded from the Class:

- (a) Defendants and their counsel, officers, directors, management, employees, subsidiaries, and affiliates;
- (b) All federal and state governmental entities except for cities, towns, municipalities or counties with self-funded prescription drug plans;
- (c) All persons or entities who purchased Bystolic for purposes of resale or directly from Defendants or their affiliates;
- (d) Fully-insured health plans (i.e., health plans that purchased insurance from another third-party payor covering 100 percent of the plan’s reimbursement obligations to its members);

- (e) Any “flat co-pay” consumers whose purchases of Bystolic were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price;
- (f) Pharmacy benefit managers; and
- (g) All judges assigned to this case and any members of their immediate families.

54. The Class is so numerous and widely geographically dispersed throughout the United States that joinder of all members is impracticable. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together. The identities of Class members will be readily ascertainable through business records kept in regular order. Plaintiff’s claims are typical of Class members. Plaintiff and all Class members were damaged by the same wrongful conduct by Defendants. Defendants’ anticompetitive conduct deprived the Class members of the benefits of competition from less-expensive generic versions of Bystolic, causing them to pay artificially inflated, supracompetitive prices for Bystolic.

55. Plaintiff will fairly and adequately protect and represent the interests of the Class. The interests of Plaintiff are aligned with, and not antagonistic to, those of the other Class members.

56. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation and have particular experience with class action antitrust litigation involving pharmaceutical products.

57. Questions of law and fact common to Class members predominate over questions, if any, that may affect only individual Class members, because Defendants have acted on grounds generally applicable to the entire Class. Such generally applicable questions are inherent in Defendants’ wrongful conduct.

58. Questions of law and fact common to the Class include:
- (a) Whether the conduct alleged herein constitutes a violation of the antitrust laws;
  - (b) Whether Defendants conspired to suppress generic competition to Bystolic;
  - (c) Whether Defendants' challenged conduct suppressed generic competition to Bystolic;
  - (d) Whether a relevant antitrust market needs to be defined in this case in light of the existence of direct proof of Defendants' power to exclude generic competition and charge supracompetitive prices for Bystolic;
  - (e) If a relevant antitrust market needs to be defined, what the definition of the relevant antitrust market for analyzing Defendants' monopoly power is, and whether Defendants had monopoly power in the relevant antitrust market;
  - (f) Whether Defendants illegally obtained or maintained monopoly power in the relevant market;
  - (g) Whether Defendants' actions were, on balance, unreasonable restraints of trade;
  - (h) Whether the Patent Settlements included large and unjustified payments in exchange for promises from the generic manufacturers to delay generic entry;
  - (i) Whether the activities of Defendants as alleged herein have substantially affected interstate commerce;
  - (j) Whether, and to what extent, Defendants' conduct caused antitrust injury (overcharges) to Plaintiff and the Class; and
  - (k) The quantum of overcharge damages paid by the Class in the aggregate.

59. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly-situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

60. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

## **V. REGULATORY BACKGROUND**

### **A. The Regulatory Structure for Approval of Drugs**

61. Under the Federal Food, Drug, and Cosmetic Act (“FDCA”), a company seeking to market a new drug must obtain the approval of the FDA by filing a New Drug Application (“NDA”). 21 U.S.C. §§ 301-92. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as information on applicable patents. 21 U.S.C. §§ 355(a), (b).

62. When the FDA approves a brand manufacturer’s NDA, the brand manufacturer may list in the FDA’s book of Approved Drug Products with Therapeutic Equivalence Evaluations (called the “Orange Book”) any patent that it certifies (1) claims either the approved drug product or approved methods of using the drug product, and (2) could reasonably be asserted against a generic manufacturer who makes, uses, or sells the drug product without authorization prior to the expiration of the listed patent(s). Relevant patents issued after NDA approval must be listed in the Orange Book within 30 days of issuance. 21 U.S.C. §§ 355(b)(1), (c)(2).

63. The FDA relies completely on the brand manufacturer's certification about its patents, as the FDA does not have the resources or authority to verify for accuracy or product or its use. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. *The Hatch-Waxman Amendments*

64. In 1984, Congress enacted the Hatch-Waxman Amendments to the FDCA to expedite the entry of less expensive generic competitors to brand drugs to reduce healthcare expenses nationwide, while also providing for patent term extensions and the ability to file prelaunch infringement suits to bolster pharmaceutical companies' financial incentives to create new and innovative products. *See generally* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

65. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historic revenues and profits for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did.<sup>29</sup> In 1985, prescription drug revenue for brand and generic drugs totaled \$21.6 billion; by 2018, total prescription drug revenue had climbed to more than \$344 billion, with generic drugs accounting for 90% of prescriptions.<sup>30</sup> Generics are now dispensed 97% of the time when a generic form is available.<sup>31</sup>

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<sup>29</sup> Congressional Budget Office, How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry 37 (July 1998), <https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf>.

<sup>30</sup> *See* IQVIA Institute, Medicine Use and Spending in the U.S. 2, 5 (May 2019), [https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us---a-review-of-2018-outlook-to-2023.pdf?\\_=1591811126454](https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us---a-review-of-2018-outlook-to-2023.pdf?_=1591811126454).

<sup>31</sup> *Id.*; *see also* IMS Institute for Healthcare Informatics, Medicine Use and Shifting Costs of Healthcare 30, 51 (Apr. 2014),

66. The Hatch-Waxman Amendments simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. A manufacturer seeking approval to sell a generic version of a brand drug may instead file an ANDA. An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's NDA. The ANDA applicant must further show that the generic drug is bioequivalent (i.e., that the active ingredient of the proposed generic drug is absorbed in the patient's blood stream to the same extent and for the same amount of time as the brand counterpart, 21 U.S.C. § 355(j)(8)(B)), and that it is pharmaceutically equivalent (e.g., that it contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug). Generic drugs that are both bioequivalent and pharmaceutically equivalent are considered "therapeutically equivalent" to the brand drug. *See generally* 21 U.S.C. §355(j) *et seq.*

67. The FDCA and Hatch-Waxman Amendments operate on the proven scientific principle that therapeutically equivalent drugs are substitutable. Generic drugs that are therapeutically equivalent to their brand counterparts are given an "AB" rating by the FDA, a designation which causes a pharmacy presented with a prescription for the brand to automatically dispense the generic instead.

## 2. Paragraph IV Certifications

68. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

- i. That no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

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<https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/IMS-Medicine%20use%20and%20shifting%20cost%20of%20healthcare.pdf>.

- ii. That the patent for the brand drug has expired (a “Paragraph II certification”);
- iii. That the patent of the brand drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a “Paragraph III certification”); or
- iv. That the patent for the brand drug is invalid, unenforceable, and/or will not be infringed by the generic manufacturer’s proposed product (a “Paragraph IV certification”).

21 U.S.C. § 355(j)(2)(A)(vii).

69. To obtain FDA approval of an ANDA prior to the expiration of a patent or patents listed in the Orange Book, a generic manufacturer must file a Paragraph IV certification and serve timely notice to the brand manufacturer. The filing of an ANDA with a Paragraph IV certification gives rise to a cause of action for patent infringement pursuant to 35 U.S.C. § 271(e)(2). If the brand manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notice of the Paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of thirty months (the “30-month stay”), or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer’s ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). The FDA may grant tentative approval to an ANDA when it determines that the ANDA would otherwise be ready for final approval but for the existence of an unexpired patent for which the generic filer has submitted a Paragraph III certification (i.e., that the generic does not intend to market the ANDA product prior to the expiration of the patent) or the existence of a regulatory exclusivity, such as the 30-month stay.

### 3. *First-Filer’s 180-Day Exclusivity Period*



70. Generics may be classified as (1) first-filer generics, (2) later-filing generics, or (3) the brand's own authorized generic.

71. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first generic manufacturer who files an ANDA with a Paragraph IV certification (the "first-filer") a 180-day period to market the generic version of the drug, during which the FDA may not grant final approval to any other later-filing generic manufacturer's ANDA for the same brand drug. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D). That is, when a first-filer files a substantially complete ANDA with the FDA and certifies that at least one unexpired patent listed in the Orange Book as covering the brand product is either invalid, unenforceable, or not infringed by the generic's product, the FDA cannot approve a later-filing generic company's ANDA until that first-filer generic has been on the market for 180-days, or until the first-filer's 180-day exclusivity has been forfeited. The 180-day window is referred to as the first-filer's 180-day "exclusivity" or "exclusivity period."

72. By contrast, a first-filer that informs the FDA that it intends to wait until all Orange Book listed patents expire before marketing its product (e.g., one that files a Paragraph III certification as to all Orange Book-listed patents) will not receive a 180-day exclusivity period. Congress created the 180-day exclusivity period to incentivize generic manufacturers to file Paragraph IV certifications challenging weak patents, or to invent around such patents by creating non-infringing generics.

73. The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly worth several hundred million dollars" to the first-filer.<sup>32</sup>

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<sup>32</sup> *FTC v. Actavis, Inc.*, 570 U.S. 136, 133 S. Ct. 2223, 2229 (2013) (internal citation and quotation marks omitted).

74. An authorized generic, or AG, is simply the brand product, sold or licensed by the brand for sale, under generic trade dress, at a cheaper price than the brand price. Because the AG is already approved under the brand manufacturer's NDA, it can be marketed at any time, including during the first-filer's 180-day exclusivity period.<sup>33</sup>

75. A brand can also license a first-filer generic competitor to launch an authorized generic. The first-filer's launch of an authorized generic triggers its 180-day exclusivity period.

### **B. The Benefits of AB-Rated Generic Competition**

76. Since the FDA deems AB-rated generic versions of brand drugs to be just as safe and effective as their brand counterparts, the only material mode of differentiating the two is their price. On average, generics are at least 10% less expensive than their brand counterparts when there is a single generic competitor. This discount typically increases to 50-80% (or more) when there are multiple generic competitors on the market for a given brand.

77. Every state has adopted laws that either require or permit pharmacies to automatically substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician has affirmatively requested the brand). Accordingly, once one generic equivalent enters the market, the generic quickly captures sales of the corresponding brand drug, often capturing 80% or more of the brand's sales within the first six months.

78. The Federal Trade Commission ("FTC") found that by 12 months after generic entry, generics on average capture 90% of corresponding brand drug sales and (with multiple generics on the market) prices drop 85% relative to brand prices.<sup>34</sup> That is because, once

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<sup>33</sup> See, e.g., FDA, Guidance for Industry, 180-Day Exclusivity: Questions and Answers at 13, <https://www.fda.gov/media/102650/download>.

<sup>34</sup> See FTC, Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions at 8 (Jan. 2010) ("FTC Pay-for-Delay Study"),

multiple generic competitors enter, the competitive process accelerates and multiple generic sellers typically compete vigorously with each other for market share by driving prices further down toward marginal manufacturing costs.<sup>35</sup> As a result, competition from generic drugs is viewed by brand drug companies, such as AbbVie, as a grave financial threat.

79. By contrast, generic competition enables purchasers (like Class members here) to purchase substantially less expensive generic versions of a drug instead of the more expensive brand, and to purchase generic versions of a drug at increasingly lower prices as more generic versions of that brand drug enter the market. In addition, generic competition enables purchasers to pay lower prices for their remaining brand drugs when the brand company lowers its brand price to compete with the generic for sales.

80. Once exclusivity is lost and generic entry occurs—an event sometimes referred to as the “patent cliff”—the brand manufacturer can expect a significant drop in profits, as it is forced to either compete by dramatically lowering prices, or accept dramatically lower sales. The tradeoff of longer exclusivity rights in return for quick and effective generic entry after loss of exclusivity was fundamental to the policies and procedures that Congress established in the Hatch-Waxman Act, and embraced by the states in their generic substitution laws. “According to the Congressional Budget Office, generic drugs save consumers an estimated \$8

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<http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-payoffs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>.

<sup>35</sup> See, e.g., Patricia Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, 43 J.L. & Econ. 311, 314, 339-41, 354-55 (2000).

to \$10 billion a year at retail pharmacies. Billions more are saved when hospitals use generics.”<sup>36</sup>

**C. Brand and Generic Companies Have Strong Financial Incentives to Agree to Anticompetitive Terms**

81. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. Brand manufacturers, such as Defendants, are well aware of generics’ rapid erosion of their brand sales, and thus seek to delay and stall the impact of generic competition for as long as possible, sometimes (as here) resorting to illegal means.

82. One way that brand manufacturers game the system, causing an anticompetitive effect, is by paying generic manufacturers to delay entering the market. These agreements not to compete are sometimes referred to as or “pay-for-delay agreements,” and they have long concerned the FTC. Brand and generic manufacturers execute pay-for-delay agreements to take advantage of the regulatory consequences associated with the generic manufacturers’ Paragraph IV certifications.

83. In a typical pay-for-delay agreement, the brand manufacturer pays a generic manufacturer to delay or abandon market entry. The brand manufacturer preserves its monopoly by effectively paying some of its monopoly profits to the generic manufacturer, which in turn agrees to delay marketing its product. Because of the sharp price drop that would result from generic competition, both the brand and the generic manufacturer can make

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<sup>36</sup> *Generic Drugs Undergo Rigorous FDA Scrutiny*, U.S. Food & Drug Admin. (Oct. 8, 2014), <https://www.fda.gov/consumers/consumer-updates/generic-drugs-undergo-rigorous-fda-scrutiny>.

more money from this arrangement than from competing against each other for increasingly smaller margins.

84. Pay-for-delay agreements often take the form of settlement agreements to end patent infringement suits filed by brand manufacturers when they get notice of an ANDA with a Paragraph IV certification concerning one or more of their patents. Instead of defending their patents in court, as the Hatch-Waxman Act's drafters intended, the brand company pays the generic manufacturer to stay off the market, allowing both companies to benefit from monopoly profits. These agreements are also called "reverse-payment agreement," because the plaintiff pays the defendant to end the suit—the opposite of what normally happens in a civil settlement.

**D. Pay-for-Delay Agreements with First-Filers Can Create Bottlenecks for Later-Filing Generics**

85. An anticompetitive agreement entered into between the brand and the first-filer generic often creates a bottleneck preventing the later ANDA filers from launching, since the later ANDA filers cannot launch earlier than 180 days after the first-filer's launch.

86. Later ANDA filers have more modest financial prospects than the first-filer generic because the later filers have no expectation of any form of market exclusivity, such as the first-filer's 180-day exclusivity. By the time the later ANDA filers enter the market, they typically must compete with the brand, the first-filer, an authorized generic, and other later filers.

87. Nevertheless, in the absence of an anticompetitive agreement between the brand company and the first-filer, the later ANDA filers have procompetitive incentives. They are motivated to enter the market as early as possible because the sooner they enter, the sooner they can earn profits by competing for sales in the market, which results in lower prices.

88. However, later ANDA filers cannot obtain final FDA approval to enter the market until the first-filer's 180-day exclusivity has run or been forfeited. An agreement between the brand and the first-filer that delays the first-filer's entry thus creates a bottleneck that, by delaying the first filer's 180-day exclusivity, consequently delays the later ANDA filers' entry as well.

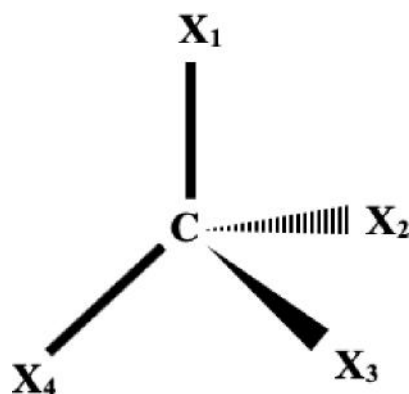
89. Agreements causing such bottlenecks are fundamentally anticompetitive and are contrary to the goals of the Hatch-Waxman statutory scheme. In particular, they extend the brand manufacturer's monopoly profits by blocking and delaying access to more affordable generic drugs, forcing purchasers to buy the more expensive brand drug instead.

## VI. FACTUAL ALLEGATIONS

### A. Basic Chemistry Relating to the Active Pharmaceutical Ingredient in the Drug Product Bystolic

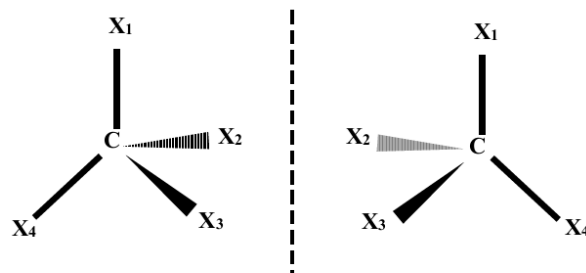
90. Molecules are composed of atoms (*e.g.*, carbon, nitrogen or hydrogen) that are bonded to each other through the sharing of electrons. The atom carbon forms four bonds and tends to adopt a tetrahedral structure. That three-dimensional arrangement can be envisioned as a tetrahedron with the carbon atom at the center and the four substituents at the four vertices of the tetrahedron.

91. The chemical symbol for a carbon atom is "C." The figure below depicts a carbon atom (labeled as "C") bonded to four different chemical substituents (labeled as "X1," "X2," "X3," and "X4"). The straight lines from the carbon atom (at the center) to "X1" and "X4" are



intended to convey that they are in the plane of the page. The solid wedge from the carbon atom to “X3” is intended to convey that it is coming out of the page towards the reader. And the hashed wedge from the carbon atom to “X2” is intended to convey that it is coming out of the page but away from the reader. Thus, the above figure reflects a three-dimensional tetrahedral structure with a carbon atom at its center.

92. When a carbon atom is attached to four different substituents in a tetrahedral arrangement such as that shown above, the substituents can be arranged in either of two conformations, as depicted below, with a mirror line between them. Note that, much like one’s left and right hands, these two arrangements are mirror images of one another. And, much like one’s left and right hands, they cannot be superimposed on one another by rotation. A carbon atom bonded to four different substituents can thus exist as either of two “stereoisomers” and such a carbon atom is referred to as a “chiral center.” Naming conventions exist to distinguish these two stereoisomers from one another, and a commonly used terminology refers to one configuration as the “R” configuration and the other as the “S” configuration.

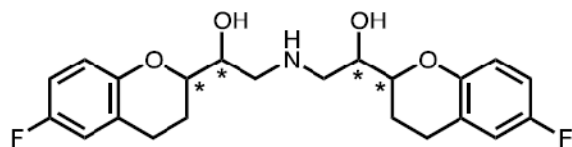


93. Distinguishing between stereoisomers can be particularly important in biological systems because many active pharmaceutical ingredients (“APIs”) in drugs interact with naturally occurring receptors in the human body by fitting into a three-dimensional site on the receptor, much like a left hand fits into a left-handed glove. Just as a left hand would not fit properly into a right-handed glove, the wrong stereoisomer often will not fit into the intended receptor site. Thus, it is not uncommon for one stereoisomer to exhibit a desired pharmacological activity in biological systems while the other does not.

94. Carbon is so ubiquitous in organic chemicals that a carbon atom in chemical structures is often abbreviated as a vertex, rather than as a “C,” with the understanding that such vertices are carbon. The chemical symbol for hydrogen is “H” and hydrogen only forms one bond. Because hydrogen is also ubiquitous and the number of chemical bonds that carbon and hydrogen make (*i.e.*, 4 and 1, respectively) is so well known, hydrogen is often omitted from chemical structures and its presence is assumed when a carbon has less than four bonded substituents.

95. On March 31, 1987, the United States Patent and Trademark Office (“PTO”) issued United States Patent No. 4,654,362 (“the ‘362 Patent”). The ‘362 Patent disclosed a number of different chemical compounds, including the following chemical compound:





96. The unlabeled vertices above correspond to a carbon atom and each of those carbon atoms (vertices) is connected to other atoms. To the extent a particular carbon atom has less than four bonds depicted, the remainder are hydrogen atoms. With this understanding in mind, each asterisk in the above chemical structure corresponds to a chiral center – *i.e.*, a carbon atom bonded to four different substituents – that can adopt either of two configurations that can be labeled as either an “R” or “S” configuration. As a result, the above chemical structure discloses ten different possible stereoisomers with the following configurations:

- |         |          |
|---------|----------|
| 1. SRRR | 6. SRSS  |
| 2. RSSS | 7. RSRR  |
| 3. SRRS | 8. RRSS  |
| 4. RSSR | 9. SSSS  |
| 5. SRSR | 10. RRRR |

97. Forest was, and its successor in interest Allergan is, the holder of NDA No. 21-742 for Bystolic. The active ingredient in Bystolic is a mixture of two of the above ten stereoisomers: the SRRR and RSSS stereoisomers (*i.e.*, nos. 1 and 2, above). The mixture of these two stereoisomers is referred to as nebivolol, and both are present in Bystolic as a hydrochloride salt.

#### **B. Forest’s Bystolic Patents**

98. Forest certified to the FDA that the ’040 and ’580 Patents covered Bystolic, and FDA listed those patents in the Orange Book. The ’580 Patent was issued on June 2, 1998 and

expired seventeen years later, on June 2, 2015. Accordingly, the '580 Patent afforded Forest no protection from generic competition for Bystolic beyond June 2, 2015.

99. The '040 Patent issued from United States Application Serial No. 07/825,488 (“the '488 Application”) was filed on January 24, 1992. To understand the impact of the prosecution of the '488 Application at the PTO on the scope of the issued claims in the '040 Patent, it is important to understand the effect of the choice of transition in a patent claim. “A patent claim typically has three parts: the preamble, the transition, and the body.” Donald S. Chisum, CHISUM ON PATENTS § 8.06[1](b) (2003). “The preamble is an introductory phrase that may summarize the invention, its relation to the prior art, or its intended use or properties.” *Id.* § 8.06[1](b)[i]. “The transition is a phrase connecting the preamble to the body of the claim. The content of the phrase may indicate whether the elements stated in the body are ‘open’ or ‘closed.’” *Id.* § 8.06[1](b)[ii]. “The body of the claim is the recitation or listing of the elements and limitations which define the product or process to be encompassed within the patent monopoly.” *Id.* § 8.06[1](b)[iii].

100. There are three commonly used transitional phrases: “comprising,” “consisting of,” and “consisting essentially of.” *Id.* § 8.06[1](b)[ii]; *Conoco, Inc. v. Energy & Envtl. Int’l, L.C.*, 460 F.3d 1349, 1360 (Fed. Cir. 2006). These are “terms of art in patent law that ‘define the scope of the claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim.’” *Id.* (quoting the Manual of Patent Examining Procedures). At one end of the spectrum, the phrase “comprising” signifies that the claim is “open” to the addition of unrecited components or steps. *CIAS, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007). For example, a claim reciting a product “comprising” three ingredients A, B and C encompasses a product composed of A, B, C and D (*i.e.*, the addition of D to the A-B-C combination does not avoid infringement).

101. The originally-filed claims in the application that issued as the '040 Patent employed the open transition “comprising.” For example, originally-filed claim 19 covered pharmaceutical compositions “comprising” a “pharmaceutically acceptable carrier” and the SRRR and RSSS stereoisomers of nebivolol. The use of the open transition “comprising” meant that original claim 19 covered formulations having the SRRR and RSSS stereoisomers of nebivolol, even if the formulations also included some or all of the other eight unclaimed stereoisomers of nebivolol. The PTO examiner therefore rejected those claims based upon the prior art '362 Patent described above. The examiner reasoned that the '362 Patent taught mixtures of various of the stereoisomers described above, and thus were covered by pending claim 19.

102. In response, the applicants admitted that the '362 Patent taught “undefined mixtures that may include the presently claimed compounds in admixture with other stereoisomers of the Base Compound. . . .” More specifically, the applicants admitted that “Compound 84 . . . is an undefined mixture of the RSRR, RSSS, SRSS and SRRR isomers, and Compound 87 . . . is an undefined mixture of the RSRS, RSSR, and SRRS isomers.” In an attempt to overcome the rejection, the applicants narrowed the claims by substituting new claims utilizing the transition “consisting essentially of” rather than “comprising.” In doing so, the applicants emphasized that the purpose of the amendment was to distinguish their claims from the undefined mixtures of other nebivolol isomers disclosed in the Prior Art '362 Patent:

Claims 18 and 19 have been rewritten as new Claims 25 and 26. Claim 25 recites “A composition consisting essentially of the compound . . .”, and Claim 26 recites “A pharmaceutical composition consisting essentially of . . . [the two compounds (a) and (b)]”. This amendment is being made to more clearly distinguish the claimed invention over the prior art [‘362 Patent] which, as is explained in detail below, discloses undefined mixtures that may include the presently claimed compounds in admixture with other stereoisomers of [nebivolol]. Favorable consideration of the amended claims is respectfully requested.

103. The transition “consisting essentially of” in a patent claim narrows the claim relative to “comprising.” *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003). “[W]ith respect to a ‘consisting essentially of’ claim, there is no infringement where the accused product contains additional, unclaimed ingredients that materially affect the basic and novel properties of the invention.” *Yoon Ja Kim v. Conagra Foods, Inc.*, 465 F.3d 1312, 1320-21 (Fed. Cir. 2006). Thus, for a claim reciting a product “consisting essentially of” ingredients A, B and C, the addition of unrecited ingredient D will avoid infringement if D has a material effect on the basic and novel properties of the claimed invention.

104. The PTO examiner, however, was not persuaded that the use of the “consisting essentially of” transition distinguished the then-pending claims from the ’362 Patent. He therefore maintained his rejection of the claims. The applicants for the ’040 Patent again argued that it was impossible to tell from the ’362 Patent which stereoisomers, and in what amounts, were definitely present in the disclosed mixtures:

There is no way that one can determine from the teachings of the patent the specific stereoisomeric configuration of [the prior art ’362 Patent’s] compound Nos. 84 and 87.

The Examiner continued to maintain his rejections and ultimately issued a final rejection of the “consisting essentially of” Claims 25 and 26, as anticipated by the ’362 Patent. He also rejected the claims as obvious.

105. The applicants for the ’040 Patent appealed the examiner’s final anticipation and obviousness rejections to the Board of Patent Appeals and Interferences (“the Board”). In their brief, the applicants continued to argue that it was impossible to say exactly which stereoisomers (and how much of them) were present in Compound 84 of the prior art ’362 Patent, but that the “possible” stereoisomers present in unknown amounts were RSRR, RSSS,

SRRR and SRSS. During the course of briefing the appeal to the Board, the Examiner dropped the anticipation rejection.

106. The Board nevertheless addressed the anticipation issue and made certain findings and conclusions regarding the relationship between then-pending Claim 26 and Compound 84 of the '362 Patent. Specifically, the Board concluded:

[The '362 Patent's] disclosure of compound 84, together with its designation "AB," appears to describe the individual RSSS, SRRR, RSRR and SRSS stereoisomers "just as surely as if they were identified in the reference by name."

107. The Board then determined that the "consisting essentially of" transition in then-pending Claim 26 caused the claim to cover the undefined mixture of isomers in the Prior Art '362 Patent:

It is well settled that "the phrase 'consisting essentially of' limits the scope of a claim to the specified ingredients and those that do not materially affect the basic and novel characteristic(s) of a composition." Here, a basic and novel characteristic of the pharmaceutical composition of claim 26 is its blood pressure reducing or antihypertensive effect. Thus, claim 26 is open to ingredients that do not materially affect its antihypertensive activity. [The prior art '362 Patent's] antihypertensive compound 84 is a mixture of four stereoisomers: RSSS, SRRR, RSRR and SRSS. ***Because the RSSR and SRSS stereoisomers do not materially affect blood pressure reducing or antihypertensive activity, it appears that they are not excluded from the composition of claim 26.***

(internal citation omitted and emphasis added). Accordingly, the Board ordered the Examiner to reconsider his withdrawal of the anticipation rejection based on the Prior Art '362 Patent:

Specifically, the examiner should consider whether claim 26 'reads on' [the '362 Patent's] compound 84 taking into account the appropriate principles of claim interpretation and the foregoing remarks.

The very clear upshot of the Board's decision was that the claims of the '488 Application were not patentable unless the claims excluded the unclaimed stereoisomers, particularly the RSSR and SRSS stereoisomers.

108. On remand from the Board, the applicants for the '040 Patent did not even attempt to argue against anticipation in view of the Board's opinion. Instead, they further narrowed their claims by replacing "consisting essentially of" with "consisting of," in new Claims 27 and 28. And based on that change, applicants argued that the new "consisting of" limitation excluded the undefined mixture of possible stereoisomers in the '362 Patent:

Applicants respectfully submit that the claims, as amended, are patentable over [the prior art '362 Patent]. Applicants submit that neither a composition consisting of the RSSS enantiomer, nor a composition consisting of the RSSS enantiomer and its enantiomer the SRRR enantiomer, are disclosed in [the '362 Patent]. [The '362 Patent] discloses the base compound, as an undefined mixture of stereoisomers, as compound 84 (designated as "AB") and 87 (designated as "AA"), shown in the table in Col. 21 of the patent.

109. Once again, the applicants expressly noted that "Compound 84 [of the prior art '362 Patent] is an undefined mixture of the RSRR, RSSS, SRSS and SRRR isomers, and Compound 87 [ ] is an undefined mixture of the RSRS, RSSR, and SRRS isomers." They argued that the new "consisting of" language excluded compounds containing such additional isomers:

[I]t is clear that the cited [the '362 Patent] discloses neither a composition consisting of the RSSS enantiomer of the base compound, nor a composition consisting of the RSSS and SRRR enantiomers.

110. And again, applicants did not distinguish their claims based on any particular amount or source of possible unrecited stereoisomers in the "undefined mixture" of the '362 Patent.

111. The phrase "consisting of" is the narrowest of the transitions and it "signifies restriction and exclusion of unrecited steps or components." Manual of Patent Examining Procedures § 2111.03; *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed. Cir. 2004). In light of the Board's reasoning and the applicants' comments and amendments, it is clear that the narrowing amendment was intended to and did exclude the presence of the unclaimed

stereoisomers, particularly the RSSR and SRSS stereoisomers (*i.e.*, the claims do not cover formulations containing the unclaimed stereoisomers, especially the RSSR and SRSS stereoisomers).

112. The Examiner then allowed the “consisting of” Claims 27 and 28, which ultimately issued as Claims 2 and 3 of the ’040 Patent in 2003.

113. Subsequently, the ’040 Patent was subjected to reexamination proceedings and a reexamination certificate issued in 2009.

### **C. Forest’s Bystolic Patents**

114. Alkem, Amerigen, Glenmark, Indchemie, Hetero, Torrent and Watson were the first generic manufacturers to file ANDAs with the FDA containing Paragraph IV certifications regarding Bystolic patents. For example, in letters granting final approval to their ANDAs, the FDA noted that each was “one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Nebivolol Tablets.”<sup>37</sup>

115. Because the Generic Competitors were the first companies to file substantially complete ANDAs with Paragraph IV certifications, they each stood to receive 180 days of marketing exclusivity during which the FDA would not give final approval to any later ANDA filer’s generic equivalent of Bystolic.

116. Forest received the Generic Competitors’ Paragraph IV notice letters on the following dates:

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<sup>37</sup> See, e.g., 11/27/2015 Letter from FDA to Watson, [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2015/203683Orig1s000Ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203683Orig1s000Ltr.pdf); 5/27/2017 Letter from FDA to Glenmark, [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2017/203821Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/203821Orig1s000ltr.pdf); 6/24/2015 Letter from FDA to Alkem, [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2015/203741Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203741Orig1s000ltr.pdf).

- Torrent: February 2, 2012<sup>38</sup>
- Indchemie: February 3, 2012<sup>39</sup>
- Alkem: February 3, 2012<sup>40</sup>
- Watson: February 13, 2012<sup>41</sup>
- Amerigen: February 16, 2012<sup>42</sup>
- Glenmark: February 20, 2012<sup>43</sup>
- Hetero: February 17, 2012<sup>44</sup>

117. Because they contained Paragraph IV certifications, these notice letters were required to include a detailed statement of the factual and legal bases as to why the '040 Patent was invalid, unenforceable, and/or not infringed by their ANDA products. The Paragraph IV notice letters were required to include an offer of confidential access to each Generic Competitor's ANDA under the Hatch-Waxman Act. The notice letters gave rise to a potential cause of action for patent infringement, thereby allowing Forest to file suit against the Generic Competitors under the Hatch-Waxman Act (if Forest otherwise had a basis to sue under Rule 11).

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<sup>38</sup> *Forest Laboratories, et al., v. Torrent Pharmaceuticals Ltd. et al.*, 12-cv-05030 (D. Del. Mar. 13, 2012) (ECF No. 1 ¶ 93).

<sup>39</sup> *Forest Laboratories, et al. v. Indchemie Health Specialties PVT et al.*, 12-cv-01855 (N.D. Ill. Mar. 14, 2012) (ECF No. 1 ¶ 22).

<sup>40</sup> *Id.* ¶ 38.

<sup>41</sup> *Forest Laboratories, et al., v. Torrent Pharmaceuticals Ltd. et al.*, 12-cv-05030 (D. Del. Mar. 13, 2012) (ECF No. 1 ¶ 108).

<sup>42</sup> *Id.* ¶ 123.

<sup>43</sup> *Id.* ¶ 138.

<sup>44</sup> *Id.* ¶ 153.



#### D. The Bystolic Patent Litigation

118. On March 13, 2012, in response to their Paragraph IV certification letters, Forest filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Torrent, Watson, Amerigen, Glenmark, and Hetero.<sup>45</sup>

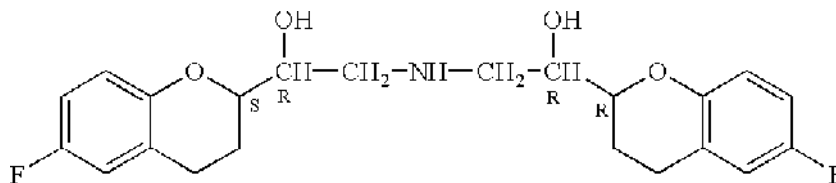
119. On March 14, 2012, in response to their Paragraph IV certification letters, Forest filed a patent infringement lawsuit in the United States District Court for the Northern District of Illinois against Indchemie and Alkem.<sup>46</sup>

120. By order of the Judicial Panel for Multidistrict Litigation, these cases were consolidated into *In re Nebivolol Patent ('040) Litigation*, 12-cv-5026 (N.D. Ill. June 12, 2012) (ECF No. 1) (hereafter referred to as the “Nebivolol Patent Litigation”).

121. Forest could not prevail in the Nebivolol Patent Litigation. The sole independent claim asserted by Forest in the Bystolic Patent Litigation was claim 2, as shown below:

2. A pharmaceutical composition consisting of a pharmaceutically acceptable carrier and, as active ingredients:

(a) the blood pressure reducing compound  $[2S, \alpha R, 2'R, \alpha'R]-\alpha, \alpha'$  [iminobismethylene]bis[6-fluoro-3,4-dihydro-2H-1-benzopyran-2-methanol] having the formula:

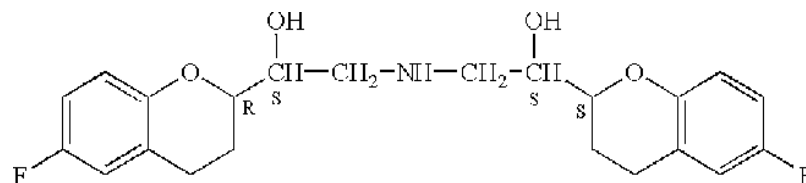


<sup>45</sup> *Forest Laboratories, et al., v. Torrent Pharmaceuticals Ltd. et al.*, 12-cv-05030 (D. Del. Mar. 13, 2012) (ECF No. 1).

<sup>46</sup> *Forest Laboratories, et al. v. Indchemie Health Specialties PVT et al.*, 12-cv-01855 (N.D. Ill. Mar. 14, 2012) (ECF No. 1).

or a pharmaceutically acceptable acid addition salt thereof; and

(b) the compound  $[\alpha R, \alpha S, 2'S, 2'S']\text{-}\alpha, \alpha'\text{-}[\text{iminobismethylene}]\text{bis}[6\text{-fluoro-3,4-dihydro-2H-1-benzopyran-2-methanol}]$  having the formula:



or a pharmaceutically acceptable acid addition salt thereof.

'040 Patent at 11:33-12:22. Thus, claim 2 is limited to a pharmaceutical composition consisting of a pharmaceutically acceptable carrier and, as active ingredients, SRRR-nebivolol and RSSS-nebivolol (or pharmaceutically acceptable acid addition salts).

122. The Generic Competitors were well aware of the prosecution history of the '040 Patent and the narrowing amendments the applicants had made. During claim construction proceedings in the Nebivolol Patent Litigation, they correctly argued that the term “consisting of” in claim 2 of the '040 Patent “excludes any unrecited stereoisomers of nebivolol.” The Generic Competitors’ products did not infringe because they included at least small amounts of the unrecited stereoisomers of nebivolol, including the RSSR and SRSS stereoisomers.

123. Early on in the Bystolic Patent Litigation, the Generic Competitors pressed the argument that the “consisting of” transition precluded the use of a plurality of inactive ingredients. Their position was premised on the argument that (1) a “pharmaceutically acceptable carrier” referred to an individual inactive ingredient in a pharmaceutical formulation; (2) the “consisting of” transition “closed” the claim to unrecited inactive ingredients; and (3) therefore, the claims did not cover formulations having two or more inactive ingredients. At least one other court has construed “pharmaceutically acceptable carrier” to mean “a conventional pharmaceutically acceptable excipient or additive. . . .” *Schering Corp. v. Mylan Pharms., Inc.*, 2011 U.S. Dist. LEXIS 63825, at \*36 (D.N.J. Jun. 15, 2011). To the extent this

interpretation applied in the Nebivolol Patent Litigation, the Generics' products did not infringe for this additional reason.

124. As a result of the foregoing, Forest could not prevail in proving literal infringement of the asserted claims of the '040 Patent. And, in light of the prosecution history of the '040 Patent, Forest could not prevail based on the doctrine of equivalents. In addition, Forest's invalidity defenses concerning the asserted claims of the '040 Patent were weak and it could not have prevailed against the Generics' invalidity arguments. As the Board explained during the prosecution of the '040 Patent:

[The '362 Patent's] disclosure of compound 84, together with its designation "AB," appears to describe the individual RSSS, SRRR, RSRR and SRSS stereoisomers "just as surely as if they were identified in the reference by name."

The '362 Patent was prior art to the '040 Patent. In light of the '362 Patent's essentially explicit teaching of a mixture of "the individual RSSS, SRRR, RSRR and SRSS stereoisomers" of nebivolol, the asserted compositions in the '040 Patent were anticipated by, or obvious in view of, the prior art, including other pertinent prior art such as Van de Water et al., Pharmacological and Hemodynamic Profile of Nebivolol, a Chemically Novel, Potent, and Selective B1-Adrenergic Antagonist, *Journal of Cardiovascular Pharmacology*, 11, No. 5, 552-563 (1988). Any purported evidence of secondary indicia of nonobviousness was insufficient to overcome the clear prima facie obviousness of the claims.

#### **E. Forest Enters into Unlawful Reverse-Payment Agreements with the Generic Competitors**

125. Starting on October 24, 2012, Forest began entering into settlements with Generic Competitors to resolve the Nebivolol Patent Litigation. Forest's internal and external counsel have conceded that each of these settlements also included "side-deals":



126. These side-deals were also listed in Forest’s Merger Agreement with Actavis, as “material contracts” that on information and belief “involve payments . . . of consideration in excess of \$15,000,000.”<sup>47</sup> In addition, Forest has also admitted that it reimbursed “certain of the Settling Defendants’ legal costs in connection with the patent litigation.”<sup>48</sup> Accordingly, on information and belief, Forest paid each Generic Competitor at least \$15,000,000 but likely more, in reverse-payments to resolve the Nebivolol Patent Litigation and induce the Generic Competitors to quit the patent fight.

<sup>47</sup> *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22 at 69).

<sup>48</sup> <https://www.sec.gov/Archives/edgar/containers/fix010/38074/000003807413000024/R17.htm>.

127. The **Hetero** reverse-payment included the “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and Hetero USA Inc. and Hetero Labs Ltd. dated October 24, 2012,” plus payment for Hetero’s expended litigation costs, and a “FINAL TERM SHEET between Hetero Drugs Ltd. and Forest Laboratories Ireland Ltd. dated October 5, 2012, in connection with the settlement of BYSTOLIC patent dispute.”<sup>49</sup>

128. On information and belief, in addition to the monies Forest paid Hetero for Hetero’s expended litigation costs, pursuant to the “FINAL TERM SHEET,” Forest paid Hetero more than \$15,000,000.

129. The **Torrent** reverse-payment included the “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. dated November 21, 2012,” plus payment for Torrent’s expended litigation costs, and a “PATENT ASSIGNMENT AGREEMENT between Torrent Pharmaceuticals Ltd and Forest Laboratories Holdings Ltd. dated November 21, 2012, in connection with the settlement of BYSTOLIC patent dispute.”<sup>50</sup>

130. On information and belief, in addition to the monies Forest paid Torrent for Torrent’s expended litigation costs, pursuant to the “PATENT ASSIGNMENT AGREEMENT,” Forest paid Torrent more than \$15,000,000.

131. The **Alkem** reverse-payment included the “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Alkem Laboratories Ltd. dated November 27, 2012,” plus payment for Alkem’s expended litigation

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<sup>49</sup> *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22 at 179).

<sup>50</sup> *Id.*

costs, and a “TERM SHEET between Alkem Laboratories Ltd., Indchemie Health Specialties Private Ltd., and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute.” Alkem and Forest also entered into an “AMENDMENT NO. 1 TO SETTLEMENT AGREEMENT . . . on January 9, 2013.”<sup>51</sup>

132. On information and belief, in addition to the monies Forest paid Alkem for Alkem’s expended litigation costs, pursuant to the Alkem “TERM SHEET,” Forest paid Alkem more than \$15,000,000.

133. The **Indchemie** reverse-payment included the “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Indchemie Health Specialties Private Ltd. dated November 27, 2012,” plus payment for Indchemie’s expended litigation costs, and a “TERM SHEET between Alkem Laboratories Ltd, Indchemie Health Specialties Private Ltd, and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute.”<sup>52</sup>

134. On information and belief, in addition to the monies Forest paid Indchemie for Indchemie’s expended litigation costs, pursuant to the Indchemie “TERM SHEET,” Forest paid Indchemie more than \$15,000,000.

135. The **Glenmark** reverse-payment included the “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and Glenmark Generics Inc., USA and Glenmark Generics Ltd. dated December 21, 2012,” plus payment for Glenmark’s expended litigation costs, and a “COLLABORATION AND OPTION AGREEMENT between Glenmark Pharmaceuticals S.A. and Forest Laboratories Holdings

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<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

Ltd. dated December 21, 2012, in connection with the settlement of BYSTOLIC patent dispute.”<sup>53</sup>

136. On information and belief, in addition to the monies Forest paid Glenmark for Glenmark’s expended litigation costs, pursuant to the “COLLABORATION AND OPTION AGREEMENT,” Forest paid Glenmark more than \$15,000,000.

137. The **Amerigen** reverse-payment included the “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013,” plus payment for Amerigen’s expended litigation costs, and a “BINDING TERM SHEET COLLABORATION AGREEMENT between Forest Laboratories, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013, in connection with the settlement of BYSTOLIC patent dispute.”<sup>54</sup>

138. On information and belief, in addition to the monies Forest paid Amerigen for Amerigen’s expended litigation costs, pursuant to the “BINDING TERM SHEET COLLABORATION AGREEMENT,” Forest paid Amerigen more than \$15,000,000.

139. The **Watson** reverse-payment included the “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Watson Pharma, Inc., and Actavis, Inc. dated November 6, 2013,” plus payment for **Watson** expended litigation costs, and “(a) the LETTER from Forest Laboratories, Inc. to Moksha8, Inc. dated November 1, 2013 and (b) TERMINATION AND

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<sup>53</sup> *Id.*

<sup>54</sup> *Id.* at 180.

RELEASE AGREEMENT between [Watson] and Moksha8, Inc. dated November 4, 2013, in connection with the settlement of BYSTOLIC patent dispute.”<sup>55</sup>

140. On information and belief, in addition to the monies Forest paid Watson for Watson’s expended litigation costs, pursuant to the “(a) the LETTER from Forest Laboratories, Inc. to Moksha8, Inc. dated November 1, 2013 and (b) TERMINATION AND RELEASE AGREEMENT between [Watson] and Moksha8, Inc.,” Forest paid Watson more than \$15,000,000.

141. On information and belief, the value of each reverse-payment exceeded Forest’s avoided litigation costs.

142. In exchange for these reverse-payments, each Generic Competitor agreed not to compete with Forest in the market for nebivolol HCl, in which Forest had a monopoly, for so long as all others did so also, until September 17, 2021 (a mere three months prior to expiry of the ’040 Patent).<sup>56</sup>

143. The purpose and effect of the reverse-payment agreements were to delay Forest from having to face lower-priced generic competition for years.

144. But for the reverse-payment agreements, the Generic Competitors would have been ready, able, and willing to launch their generic versions of Bystolic much earlier.

145. Specifically, the Generic Competitors would have launched by the later of: (a) June 2015, which was the expiry of the only other patent that Forest contended covered Bystolic (the ’580 Patent), or (b) the date their ANDAs were finally approved.

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<sup>55</sup> *Id.*

<sup>56</sup> <https://www.sec.gov/Archives/edgar/containers/fix010/38074/000003807413000024/R17.htm>



146. By operation of the CLPs, if *just one* Generic Competitor launched a generic version of Bystolic prior to September 17, 2021 pursuant to any of the three above scenarios, *all* of the other Generic Competitors would have entered the market.

147. By about October 2012, when Forest and the Generic Competitors began entering into the reverse-payment agreements, Bystolic was generating hundreds of millions of dollars per year in revenues for Forest. Losing a substantial portion of that revenue stream in the event any of the Generic Competitors were to prevail on non-infringement or other defenses – or in the event that Forest had not induced the Generic Competitors with reverse-payments to agree to delay launching generic Bystolic – would have drastically reduced Forest's profits. Thus, Forest had enormous incentives to avoid competition from the Generic Competitors by entering into reverse-payment agreements.

148. Forest's willingness to provide large payments to each Generic Competitor in exchange for a multi-year delay in competition amounted to an agreement to share with the Generic Competitors the monopoly profits from sales of branded Bystolic at supracompetitive levels.

## **VII. EFFECTS OF THE SCHEME ON COMPETITION AND DAMAGES TO THE PLAINTIFFS AND THE CLASS**

149. U.S. sales of Bystolic were approximately \$1 billion in 2017. Forest received millions of dollars more in sales than it would have achieved absent Defendants' unlawful scheme to prevent and delay generic competition. Generic Bystolic products would have been priced at a fraction of the cost of brand Bystolic and would have quickly captured the vast majority of the market for nebivolol HCl.

150. Defendants' unlawful agreement prevented and delayed the sale of generic Bystolic in the United States and unlawfully enabled Forest to sell its branded Bystolic at

artificially inflated prices. But for Defendants' unlawful conduct, generic competitors would have been able to compete, unimpeded, with their own generic versions of Bystolic.

151. Were it not for Defendants' anticompetitive conduct, Plaintiff and other members of the Class would have purchased lower-priced generic Bystolic, instead of the higher-priced brand Bystolic, during the Class Period.

152. As a consequence, Plaintiff and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

### **VIII. MONOPOLY POWER AND MARKET DEFINITION**

153. The pharmaceutical marketplace is characterized by a "disconnect" between product selection and the payment obligation. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Bystolic, to patients without a prescription. The prohibition on dispensing certain products without a prescription creates this disconnect. The patient's doctor chooses which product the patient will buy while patient (and in most cases his or her insurer) has the obligation to pay for the product.

154. Brand manufacturers, including Forest, exploit this price disconnect by employing large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise doctors of the cost of the branded products. Studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are largely insensitive to price differences because they do not pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

155. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand – the extent to which unit sales go down

when price goes up. This reduced price elasticity, in turn, gives brand manufacturers the ability to raise prices substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise prices substantially above marginal costs is what economists and antitrust courts refer to as market power. The result of these pharmaceutical market imperfections and marketing practices is that brand manufacturers gain and maintain market power with respect to many branded prescription pharmaceuticals, including Bystolic.

156. At all relevant times, Defendants had monopoly power over nebivolol HCl products because they had the power to exclude competition and/or raise or maintain the price of the drug they sold as Bystolic at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable.

157. “[T]he ‘size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power’—namely, the power to charge prices higher than the competitive level.”<sup>57</sup> And a firm that lacks monopoly power is not “likely to pay ‘large sums’ to induce ‘others to stay out of its market.’”<sup>58</sup>

158. A small but significant, non-transitory price increase for Bystolic by Defendants would not have caused a significant loss of sales to non-nebivolol HCl products.

159. Bystolic does not exhibit significant, positive cross-elasticity of demand with respect to price with any non-nebivolol HCl product. Indeed, Defendants have never lowered the price of Bystolic in response to the pricing of any non-nebivolol HCl treatments for high

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<sup>57</sup> *Actavis*, 570 U.S. at 157 (citation omitted).

<sup>58</sup> *Id.*

blood pressure. In fact, Defendants substantially increased the price of Bystolic – by more than 60% – over the last five years.

160. Because of its labeling, Bystolic is differentiated from all non-nebivolol HCl products.

161. Defendants needed to control only nebivolol HCl, and no other products, in order to maintain the price of Bystolic profitably at supracompetitive prices. No non-nebivolol HCl product ever rendered Defendants unable to profitably maintain or raise their prices of Bystolic without losing substantial sales. Only the market entry of competing, AB-rated generic versions would render Defendants unable to profitably maintain their prices for Bystolic without losing substantial sales.

162. Defendants also sold Bystolic at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

163. Defendants have had, and exercised, the power to exclude and restrict competition to nebivolol HCl.

164. Defendants, at all relevant times, enjoyed high barriers to entry with respect to competition to the relevant product market due to patent and other regulatory protections and high costs of entry and expansion, which protects brand Bystolic from the forces of price competition.

165. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show Defendants' ability to control the price of Bystolic, and to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, *inter alia*, the following facts: (i) generic Bystolic would have entered the market at a much earlier date, at a substantial discount to brand Bystolic, but for Defendants' anticompetitive conduct; (ii) Forest's gross margin on Bystolic (including the costs of ongoing

research/development and marketing) at all relevant times was very high; and (iii) Forest never lowered the price of Bystolic to the competitive level in response to the pricing of non-nebivolol HCl product.

166. To the extent proof of monopoly power by defining a relevant product market is required, Plaintiff alleges that the relevant antitrust market is the market for nebivolol HCl. During the period relevant to this case, Defendants have been able to profitably maintain the price of nebivolol HCl well above competitive levels.

167. The relevant geographic market is the United States, the District of Columbia, and the U.S. territories.

168. At all relevant times, Defendants' market share in the relevant market was and remains 100%, implying a substantial amount of monopoly power.

#### **IX. MARKET EFFECTS**

169. Defendants willfully and unlawfully maintained their market power by engaging in an overarching scheme to exclude competition. Defendants designed a scheme to prevent and delay competition on the products' merits, to further Forest's anticompetitive purpose of forestalling generic competition against Bystolic, in which the Generic Competitors cooperated in order to increase their own profits. Defendants carried out the scheme with the anticompetitive intent and effect of maintaining supracompetitive prices for nebivolol HCl.

170. The reverse-payments enabled Defendants to: (a) prevent and delay until September 17, 2021 the entry of less-expensive generic versions of Bystolic in the United States; (b) fix, raise, maintain, or stabilize the price of Bystolic products; and (c) allocate to themselves 100% of the U.S. market for Bystolic and its generic equivalents until September 17, 2021.

171. But for the unlawful reverse-payment agreements, the Generic Competitors would have begun selling a less expensive generic version of Bystolic much earlier than September 17, 2021. Such sales would have occurred via market entry by any of the Generic Competitors upon a Generic Competitor litigation victory, at risk (that is, while the patent litigation remained pending), or via a licensed entry in a settlement with Forest that did not include a side-deal or any other unlawful reverse-payments from Forest to any Generic Competitor.

172. An increasingly competitive market for Bystolic and its generic equivalents, with lower prices, would have thereafter emerged as additional generic versions of Bystolic (including, on information and belief, an authorized generic<sup>59</sup> version of Bystolic) entered the market. Plaintiff would have purchased generic Bystolic had it been available.

173. Defendants' acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting brand Bystolic from competition. These actions allowed Defendants to maintain a monopoly and prevent and exclude competition in the market for nebivolol HCl, to the detriment of Plaintiff and all other members of the Class.

174. Defendants' exclusionary conduct prevented and delayed generic competition and unlawfully enabled Forest to sell Bystolic without further generic competition. Were it not for Defendants' illegal conduct, one or more additional generic versions of Bystolic would have entered the market.

175. Defendants' unlawful concerted action has (a) delayed and suppressed the sale of generic versions of Bystolic in the United States, (b) enabled Defendants to sell Bystolic at

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<sup>59</sup> An authorized generic is a drug manufactured under the brand's New Drug Application and licensed or sold by the brand name manufacturer with generic trade dress.

artificially inflated, supracompetitive prices, and (c) caused Plaintiff and the Class to pay supracompetitive prices for nebivolol HCl tablets.

176. Defendants' illegal acts and conspiracy to delay generic competition for Bystolic caused Plaintiff and all members of the Class to pay more than they would have paid for nebivolol HCl absent this illegal conduct.

177. If generic competitors had not been unlawfully prevented from entering and competing in the relevant market, End Payors, such as Plaintiff and members of the Class, would have paid less for nebivolol HCl by: (i) paying lower prices on their brand purchases of Bystolic, (ii) substituting purchases of less expensive generic Bystolic for their purchases of more expensive brand Bystolic, and/or (iii) purchasing generic Bystolic at lower prices sooner.

178. Thus, Defendants' unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

## **X. ANTITRUST IMPACT**

179. During the class period, Plaintiff and members of the Class purchased substantial amounts of Bystolic indirectly from Forest and others at supracompetitive prices. As a result of Defendants' illegal conduct, Plaintiff and members of the Class were compelled to pay and did pay artificially inflated prices for their nebivolol HCl purchase requirements. Those prices were substantially greater than the prices that Plaintiff and members of the Class would have paid absent the illegal conduct alleged herein, because: (i) the price of branded Bystolic was artificially inflated by Defendants' illegal conduct; (ii) Plaintiff and Class members were deprived of the opportunity to purchase lower-priced generic versions of Bystolic instead of branded Bystolic sooner, which they would have done had they had the opportunity; and/or (3) Plaintiff and Class members would have paid lower prices for generic Bystolic.

180. As a consequence, Plaintiff and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

181. Commonly used and well-accepted economic models can be used to measure both the extent and the amount of the supracompetitive charge passed through the chain of distribution to End Payors and members of the Class.

182. General economic theory recognizes that any overcharge at a higher level of distribution in the chain of distribution for Bystolic results in higher prices at every level below. Herbert Hovenkamp, *FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE* (1994) at 624. Professor Herbert Hovenkamp goes on to state that “[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top.” He also acknowledges that “[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level.”

183. The institutional structure of pricing and regulation in the pharmaceutical drug industry assures that overcharges at the higher level of distribution are passed on to End-Payors. Wholesalers and retailers passed on the inflated prices of Bystolic to Plaintiff and members of the Class. Further, the delayed entry of generic competition at the direct purchaser level similarly injured End Payors who were equally denied, and continue to be denied, the opportunity to purchase less expensive generic Bystolic.

184. Thus, Defendants’ unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.



185. Defendants' unlawful anticompetitive conduct alleged herein enabled Forest and others to indirectly charge End Payors prices in excess of what they otherwise would have been able to charge absent their unlawful actions.

186. Prices of Bystolic were artificially inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

187. The supracompetitive prices Plaintiff and members of the Class paid are traceable to, and the direct, proximate, and foreseeable result of, Defendants' anticompetitive conduct.

188. The overcharges Plaintiff and members of the Class paid are traceable to, and the direct, proximate, and foreseeable result of, Defendants' supracompetitive pricing.

## **XI. INTERSTATE AND INTRASTATE COMMERCE**

189. Defendants' anticompetitive conduct has substantially affected intrastate, interstate and foreign commerce.

190. Defendants' anticompetitive conduct has substantial intrastate effects in that, *inter alia*, it deprived retailers within each state of access to less expensive generic Bystolic that they could sell to End-Payors within each respective state. The delayed entry of generic Bystolic, has directly affected and disrupted commerce for End-Payors within each state.

191. During the relevant time period, Bystolic was shipped into each state, and End-Payors paid for Bystolic in each state.

192. During the relevant time period, Defendants manufactured, promoted, distributed, and/or sold substantial amounts of Bystolic in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

193. As a direct result of the unlawful reverse-payment agreements, the Generic Competitors refrained from selling generic versions of Bystolic when they otherwise would have done so.

194. During the relevant time period, in connection with the purchase and sale of Bystolic, Defendants transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Bystolic.

195. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants as alleged in this Complaint were within the flow of, and have substantially affected, intrastate, interstate and foreign commerce.

## **XII. CLAIMS FOR RELIEF**

### **FIRST CLAIM FOR RELIEF**

#### **Conspiracy and Combination in Restraint of Trade Under State Law**

196. Plaintiff incorporates the allegations set forth above as if fully set forth herein.

197. During the Class Period, Defendants and Generic Competitors engaged in a continuing contract, combination or conspiracy with respect to the sale of Bystolic in unreasonable restraint of trade and commerce, in violation of the various state antitrust statutes set forth below.

198. During the Class Period, Defendants and Generic Competitors entered into illegal contracts, combinations and conspiracies in restraint of trade under which Forest agreed to make large reverse payments to Generic Competitors in exchange for their agreement to delay bringing generic Bystolic to the market until September 17, 2021. The purpose and effect of these reverse-payment agreements were to: (a) allocate to Forest 100% of the U.S.

sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

199. The Defendants and Generic Competitors' reverse-payment agreements were unlawful and the reverse payments were large and unjustified.

200. The Defendants and Generic Competitors' reverse-payment agreements harmed Plaintiff and the Class as set forth above.

201. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse payments from Forest to Generic Competitors that outweighs their harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

202. As a direct, proximate, foreseeable, and intended result of the Defendants and Generic Competitors' reverse-payment agreements in restraint of trade, as alleged herein, Plaintiff and the Class were harmed and suffered overcharge damages as aforesaid. Specifically, without a reverse-payment, Generic Competitors would have launched their generic versions of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Generic Competitors would have agreed upon earlier entry dates untainted by delay associated with the unlawful side deals and reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between any Generic Competitor and Forest would also have applied to all earlier-settling Generic Competitors, if any.

203. By engaging in the foregoing conduct, Defendants and Generic Competitors intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of the following state antitrust laws:

- a. Ariz. Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of Bystolic in Arizona by Class members and/or purchases by Arizona residents.
- b. Cal. Bus. and Prof. Code §§ 16720, *et seq.*, with respect to purchases of Bystolic in California by Class members and/or purchases by California residents.
- c. Conn. Gen. Stat. § 35-26, *et seq.*, with respect to purchases of Bystolic in Connecticut by Class members and/or purchases by Connecticut residents.
- d. D.C. Code §§ 28-4502, *et seq.*, with respect to purchases of Bystolic in the District of Columbia by Class members and/or purchases by D.C. residents.
- e. Haw. Rev. Stat §§ 480-1, *et seq.*, with respect to purchases of Bystolic in Hawaii by Class members and/or purchases by Hawaii residents.
- f. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Bystolic in Illinois by Class members and/or purchases by Illinois residents.
- g. Iowa Code §§ 553.4 *et seq.*, with respect to purchases of Bystolic in Iowa by Class members and/or purchases by Iowa residents.
- h. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Bystolic in Kansas by Class members and/or purchases by Kansas residents.
- i. Md. Code, Com. Law, Section 11-204, *et seq.*, with respect to purchases of Bystolic in Maryland by Class members and/or purchases by Maryland residents.
- j. Me. Stat. tit. 10 § 1101, *et seq.*, with respect to purchases of Bystolic in Maine by Class members and/or purchases by Maine residents.

- k. Mich. Comp. Laws §§ 445.772, *et seq.*, with respect to purchases of Bystolic in Michigan by Class members and/or purchases by Michigan residents.
- l. Minn. Stat. §§ 325D.51, *et seq.*, with respect to purchases of Bystolic in Minnesota by Class members and/or purchases by Minnesota residents.
- m. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Bystolic in Mississippi by Class members and/or purchases by Mississippi residents.
- n. Neb. Rev. Stat. §§ 59-801, *et seq.*, with respect to purchases of Bystolic in Nebraska by Class members and/or purchases by Nebraska residents.
- o. Nev. Rev. Stat. §§ 598A.060, *et seq.*, with respect to purchases of Bystolic in Nevada by Class members and/or purchases by Nevada residents.
- p. N.H. Rev. Stat. Ann. §§ 356:2, *et. seq.*, with respect to purchases of Bystolic in New Hampshire by Class members and/or purchases by New Hampshire residents.
- q. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Bystolic in New Mexico by Class members and/or purchases by New Mexico residents.
- r. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of Bystolic in New York by Class members and/or purchases by New York residents.
- s. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Bystolic in North Carolina by Class members and/or purchases by North Carolina residents.
- t. N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of Bystolic in North Dakota by Class members and/or purchases by North Dakota residents.
- u. Or. Rev. Stat. §§ 646.725, *et seq.*, with respect to purchases of Bystolic in Oregon by Class members and/or purchases by Oregon residents.

- v. P.R. Laws Ann. tit. 10 §§ 258, *et seq.*, with respect to purchases of Bystolic in Puerto Rico by Class members and/or purchases by Puerto Rico residents.
- w. R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to purchases of Bystolic in Rhode Island by Class members and/or purchases by Rhode Island residents.
- x. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchases of Bystolic in South Dakota by Class members and/or purchases by South Dakota residents.
- y. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Bystolic in Tennessee by Class members and/or purchases by Tennessee residents.
- z. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of Bystolic in Utah by Class members and/or purchases by Utah residents.
- aa. W.Va. Code §§ 47-18-43, *et seq.*, with respect to purchases of Bystolic in West Virginia by Class members and/or purchases by West Virginia residents.
- bb. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Bystolic in Wisconsin by Class members and/or purchases by Wisconsin residents.

204. Plaintiff and Class members have been injured in their business or property by reason of Defendants' violations of the laws set forth above, in that Plaintiff and Class members were: (i) denied the opportunity to purchase lower-priced generic Bystolic; and (ii) paid higher prices for Bystolic than they would have paid but for Defendants' unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Defendants' conduct unlawful.

205. Plaintiff and Class members accordingly seek damages and multiple damages as permitted by law.

**SECOND CLAIM FOR RELIEF**  
**Monopolization and Monopolistic Scheme Under State Law**

206. Plaintiff incorporates the allegations set forth above as if fully set forth herein.

207. As described above, at all relevant times prior to September 17, 2021, Defendants had and will continue to have monopoly power in the relevant market.

208. By entering into the reverse-payment agreements with the Generic Competitors, Defendants willfully and intentionally maintained, enhanced, and extended their monopoly power using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiffs and the Class thereby. Specifically, Defendants (a) allocated to themselves 100% of the market for nebivolol HCl in all strengths in the United States until September 17, 2021; (b) delayed the availability of generic versions of Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fixed and maintained, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

209. It was Defendants' conscious object to further their dominance in the relevant market by and through the anticompetitive conduct alleged herein.

210. The goal, purpose, and effect of Defendants and the Generic Competitors' reverse-payment agreements was to maintain and extend Defendants' monopoly power in violation of numerous state laws. Forest and the Generic Competitors' reverse-payment agreements were intended to and did prevent and/or delay generic competition to Bystolic and enabled Defendants to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

211. Defendants and Generic Competitors specifically intended that the reverse-payment agreements would maintain Defendants' monopoly power in the relevant market, and injure Plaintiff and the Class thereby.

212. Defendants and Generic Competitors knowingly and intentionally conspired to maintain, enhance, and extend Defendants' monopoly power in the relevant market.

213. Defendants and Generic Competitors each committed at least one overt act in furtherance of the conspiracy.

214. As a direct, proximate, foreseeable, and intended result of Defendants' monopolistic scheme and concerted monopolistic conduct, as alleged herein, Defendants unlawfully maintained, enhanced, and extended its monopoly power and Plaintiff and the Class were harmed and suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse-payment, Generic Competitors would have launched their generic versions of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Generic Competitors would have agreed upon earlier entry dates untainted by delay associated with the unlawful side-deals and reverse-payments.

215. All of Forest's corporate successors adopted Defendants' monopolistic scheme and took actions in furtherance thereof.

216. By engaging in the foregoing conduct, Defendants intentionally, willfully, and wrongfully monopolized the relevant market in violation of the following state laws:

- a. Ariz. Rev. Stat. Ann. §§ 44-1403, *et seq.*, with respect to purchases of Bystolic in Arizona by Class members and/or purchases by Arizona residents.
- b. Cal. Bus. & Prof. Code §§ 16720, *et seq.*, with respect to purchases of Bystolic in California by Class members and/or purchases by California residents.



- c. Conn. Gen. Stat. §§ 35-27, *et seq.*, with respect to purchases of Bystolic in Connecticut by Class members and/or purchases by Connecticut residents.
- d. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Bystolic in the District of Columbia by Class members and/or purchases by D.C. residents.
- e. Haw. Rev. Stat. §§ 480-9, *et seq.*, with respect to purchases of Bystolic in Hawaii by Class members and/or purchases by Hawaii residents.
- f. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Bystolic in Illinois by Class members and/or purchases by Illinois residents.
- g. Iowa Code §§ 553.5 *et seq.*, with respect to purchases of Bystolic in Iowa by Class members and/or purchases by Iowa residents.
- h. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Bystolic in Kansas by Class members and/or purchases by Kansas residents.
- i. Me. Stat. tit. 10, § 1102, *et seq.*, with respect to purchases of Bystolic in Maine by Class members and/or purchases by Maine residents.
- j. Md. Code, Com Law, Section 11-204, *et seq.* with respect to purchases of Bystolic in Maryland by Class members and/or purchases by Maryland residents.
- k. Mich. Comp. Laws §§ 445.773, *et seq.*, with respect to purchases of Bystolic in Michigan by Class members and/or purchases by Michigan residents.
- l. Minn. Stat. §§ 325D.52, *et seq.*, with respect to purchases of Bystolic in Minnesota by Class members and/or purchases by Minnesota residents.
- m. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Bystolic in Mississippi by Class members and/or purchases by Mississippi residents.
- n. Neb. Rev. Stat. §§ 59-802, *et seq.*, with respect to purchases of Bystolic in Nebraska by Class members and/or purchases by Nebraska residents.

- o. N.H. Rev. Stat. Ann. §§ 356:3, *et seq.*, with respect to purchases of Bystolic in New Hampshire by Class members and/or purchases by New Hampshire residents.
- p. Nev. Rev. Stat. §§ 598A.060, *et seq.*, with respect to purchases of Bystolic in Nevada by Class members and/or purchases by Nevada residents.
- q. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Bystolic in New Mexico by Class members and/or purchases by New Mexico residents.
- r. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of Bystolic in New York by Class members and/or purchases by New York residents.
- s. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Bystolic in North Carolina by Class members and/or purchases by North Carolina residents.
- t. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Bystolic in North Dakota by Class members and/or purchases by North Dakota residents.
- u. Or. Rev. Stat. §§ 646.730, *et seq.*, with respect to purchases of Bystolic in Oregon by Class members and/or purchases by Oregon residents.
- v. P.R. Laws Ann. tit. 10, §§ 260, *et seq.*, with respect to purchases of Bystolic in Puerto Rico by Class members and/or purchases by Puerto Rico residents.
- w. R.I. Gen. Laws §§ 6-36-7 *et seq.*, with respect to purchases of Bystolic in Rhode Island by Class members and/or purchases by Rhode Island residents.
- x. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Bystolic in South Dakota by Class members and/or purchases by South Dakota residents.
- y. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Bystolic in Tennessee by Class members and/or purchases by Tennessee residents.

z. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of Bystolic in Utah by Class members and/or purchases by Utah residents.

aa. W. Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Bystolic in West Virginia by Class members and/or purchases by West Virginia residents.

bb. Wis. Stat. § 133.03, *et seq.*, with respect to purchases of Bystolic in Wisconsin by Class members and/or purchases by Wisconsin residents.

217. Plaintiff and Class members have been injured in their business or property by reason of Defendants' violations of the laws set forth above, in that Plaintiff and Class members were: (i) denied the opportunity to purchase lower-priced generic Bystolic; and (ii) paid higher prices for Bystolic than they would have paid but for Defendants' unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Defendants' conduct unlawful.

218. Plaintiff and Class members accordingly seek damages and multiple damages as permitted by law.

**THIRD CLAIM FOR RELIEF**  
**Unfair Methods of Competition, and Unfair and Deceptive Acts**  
**In Violation of State Consumer Protection Laws**

219. Plaintiff incorporates the allegations set forth above as if fully set forth herein.

220. Defendants engaged in unfair methods of competition and unfair, unconscionable, and/or deceptive acts or practices to wrongfully perpetuate their concerted conduct to restrain trade in the relevant market.

221. As a direct and proximate result of Defendants' unfair, unconscionable, and/or deceptive conduct, Plaintiff and Class members were: (i) denied the opportunity to purchase lower-priced generic Bystolic; and (ii) paid higher prices for Bystolic than they would have paid but for Defendants' unlawful conduct.

222. The gravity of harm from Defendants' wrongful conduct significantly outweighs any conceivable utility from that conduct. Plaintiff and Class members could not reasonably have avoided injury from Defendants' wrongful conduct.

223. There was and is a gross disparity between the price that Plaintiff and the Class members paid for Bystolic and the value they received. Much more affordable generic Bystolic would have been and would be available, and prices for Bystolic would have been and would be far lower, but for Defendants' unfair, unconscionable, and deceptive conduct.

224. As a direct and proximate result of Defendants' anticompetitive, unfair, unconscionable, and/or deceptive conduct, Plaintiff and Class members were denied the opportunity to purchase generic Bystolic and forced to pay higher prices for Bystolic.

225. By engaging in such conduct, Defendants violated the following consumer protection laws:

- a. Ariz. Rev. Stat. Ann. §§ 44-1521, *et seq.*, with respect to purchases of Bystolic in Arizona by Class members and/or purchases by Arizona residents.
- b. Ark. Code Ann. §§ 4-88-101, *et seq.*, with respect to purchases of Bystolic in Arkansas by Class members and/or purchases by Arkansas residents.
- c. Cal. Bus. & Prof Code §§ 17200, *et seq.*, with respect to purchases of Bystolic in California by Class members and/or purchases by California residents.
- d. Conn. Gen. Stat. §§ 42-110b, *et seq.*, with respect to purchases of Bystolic in California by Class members and/or purchases by Connecticut residents.
- e. D.C. Code §§ 28-3901, *et seq.*, with respect to purchases of Bystolic in D.C. by Class members and/or purchases by D.C. residents.
- f. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Bystolic in Florida by Class members and/or purchases by Florida residents.

- g. Haw. Rev. Stat. §§ 481-1, *et seq.*, with respect to purchases of Bystolic in Hawaii by Class members and/or purchases by Hawaii residents.
- h. Idaho Code §§ 48-601, *et seq.*, with respect to purchases of Bystolic in Idaho by Class members and/or purchases by Idaho residents.
- i. 815 Ill. Comp. Stat. 505/1, *et seq.*, with respect to purchases of Bystolic in Illinois by Class members and/or purchases by Illinois residents.
- j. Kan. Stat. Ann. §§ 50-623, *et seq.*, with respect to purchases of Bystolic in Kansas by Class members and/or purchases by Kansas residents.
- k. Me. Stat. tit. 5, §§ 207, *et seq.*, with respect to purchases of Bystolic in Maine by Class members and/or purchases by Maine residents.
- l. Mass. Gen. Laws ch. 93A, §§ 1 *et seq.*, with respect to purchases of Bystolic in Massachusetts by Class members and/or purchases by Massachusetts residents.
- m. Mich. Comp. Laws §§ 445.901, *et seq.*, with respect to purchases of Bystolic in Michigan by Class members and/or purchases by Michigan residents.
- n. Minn. Stat. §§ 325F.68, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Bystolic in Minnesota by Class members and/or purchases by Minnesota residents.
- o. Mo. Rev. Stat. §§ 407.010, *et seq.*, with respect to purchases of Bystolic in Missouri by Class members and/or purchases by Missouri residents.
- p. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases of Bystolic in Nebraska by Class members and/or purchases by Nebraska residents.
- q. Nev. Rev. Stat. Ann. §§ 598.0903, *et seq.*, with respect to purchases of Bystolic in Nevada by Class members and/or purchases by Nevada residents.

- r. N.H. Rev. Stat. Ann. §§ 358-A:1, *et seq.*, with respect to purchases of Bystolic in New Hampshire by Class members and/or purchases by New Hampshire residents.
- s. N.M. Stat. Ann. §§ 57-12-1, *et seq.*, with respect to purchases of Bystolic in New Mexico by Class members and/or purchases by New Mexico residents.
- t. N.Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to purchases of Bystolic in New York by Class members and/or purchases by New York residents.
- u. N.C. Gen. Stat. §§ 75-1.1, *et seq.*, with respect to purchases of Bystolic in North Carolina by Class members and/or purchases by North Carolina residents.
- v. Or. Rev. Stat. §§ 646.605, *et seq.*, with respect to purchases of Bystolic in Oregon by Class members and/or purchases by Oregon residents.
- w. R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to purchases of Bystolic in Rhode Island by Class members and/or purchases by Rhode Island residents.
- x. S.D. Codified Laws §§ 37-24-6, *et seq.*, with respect to purchases of Bystolic in South Dakota by Class members and/or purchases by South Dakota residents.
- y. Tenn. Code Ann. §§ 47-18-101, *et seq.*, with respect to purchases of Bystolic in Tennessee by Class members and/or purchases by Tennessee residents.
- z. Utah Code Ann. §§ 13-11-1, *et seq.*, with respect to purchases of Bystolic in Utah by Class members and/or purchases by Utah residents.
- aa. Vt. Stat Ann. tit. 9, § 2453, *et seq.*, with respect to purchases of Bystolic in Vermont by Class members and/or purchases by Vermont residents.

bb. W. Va. Code §§ 46A-6-101, *et seq.*, with respect to purchases of Bystolic in West Virginia by Class members and/or purchases by West Virginia residents.

cc. Wis. Stat. § 100.20, *et seq.*, with respect to purchases of Bystolic in Wisconsin by Class members and/or purchases by Wisconsin residents.

226. Plaintiff and Class members have been injured in their business and property by reason of Defendants' anticompetitive, unfair, unconscionable, and/or deceptive conduct. Their injury consists of paying higher prices for Bystolic than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

227. On behalf of itself and the Class, Plaintiff seeks all appropriate relief provided for under the foregoing statutes.

#### **FOURTH CLAIM FOR RELIEF Unjust Enrichment**

228. Plaintiff incorporates the above paragraphs by reference.

229. To the extent required, this claim is pleaded in the alternative to the other claims in this Complaint.

230. Defendants have reaped and retained substantially higher profits due to their unlawful scheme.

231. Plaintiff and Class members have conferred and continue to confer an economic benefit upon Defendants in the form of profits resulting from the unlawful overcharges from Bystolic sales described herein, to the economic detriment of Plaintiff and Class members.

232. Defendants' financial gain from their unlawful conduct is traceable to overpayments for Bystolic by Plaintiff and Class members.

233. Plaintiff and Class members have no adequate remedy at law.

234. It would be futile for Plaintiff and Class members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Bystolic, as those intermediaries are not liable and would not compensate Plaintiff and Class members for Defendants' unlawful conduct.

235. Defendants have benefited from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of the ill-gotten gains resulting from the overpayments made by Plaintiff and the Class members for Bystolic sold by Defendants during the Class Period.

236. The financial benefits Defendants derived from overcharging Plaintiff and Class members for Bystolic is a direct and proximate result of Defendants' unlawful practices described herein.

237. The financial benefits Defendants derived are ill-gotten gains that rightfully belong to Plaintiff and Class members, who paid and continue to pay artificially inflated prices that inured to Defendants' benefit.

238. It would be inequitable under unjust enrichment principles under the laws of each state in the United States as well as the District of Columbia, except for Indiana and Ohio, for Defendants to be permitted to retain any of the overcharges that Plaintiff and members of the Class paid for Bystolic that were derived from Defendants' unlawful practices described herein.

239. Defendants are aware of and appreciate the benefits that Plaintiff and Class members have bestowed upon them.

240. Defendants should be compelled to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of Plaintiff and Class members.



241. Plaintiff and Class members are entitled to the amount of Defendants' ill-gotten gains resulting from their unlawful, unjust, and inequitable conduct, and to the establishment of a constructive trust consisting of such amount, from which Plaintiff and Class members may make claims on a pro rata basis.

**FIFTH CLAIM FOR RELIEF**

**Declaratory and Injunctive Relief Under Sections 1 and 2 of the Sherman Act and  
Section 16 of the Clayton Act (15 U.S.C. §§ 1-2, 26)**

242. Plaintiff incorporates the allegations set forth above as if fully set forth herein.

243. Plaintiff seeks declaratory and injunctive relief under the federal antitrust laws.

244. Plaintiff's allegations described herein constitute violations of Sections 1 and 2 of the Sherman Act.

245. Defendants effectuated a concerted scheme to unreasonably restrain trade and monopolize a market.

246. There is and was no legitimate, non-pretextual, procompetitive business justification for Defendants' conduct that outweighs its harmful effect.

247. As a direct and proximate result of Defendants' anticompetitive scheme, as alleged herein, Plaintiff and the Class were harmed as aforesaid.

248. The goal, purpose and/or effect of the scheme was to prevent and/or delay competition to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

249. Plaintiff and the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Count. Their injury consists of paying higher prices for Bystolic than they would have paid in the absence of those violations. These injuries will continue unless halted.

250. Plaintiff and the Class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), hereby seek a declaratory judgment that Defendants' conduct constitutes a violation of §§ 1 and 2 of the Sherman Act.

251. Plaintiff and the Class further seek equitable and injunctive relief pursuant to § 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct the anticompetitive effects caused by Defendants' unlawful conduct in the market for Bystolic.

### **XIII. PRAYER FOR RELIEF**

252. WHEREFORE, Plaintiff, on behalf of herself and the proposed Class, prays for judgment against all Defendants, jointly and severally, as follows:

- a. Determine that this action may be maintained as a class action pursuant to Rules 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the Class, and appoint the Plaintiff as the named representative of the Class;
- b. Grant injunctive relief that restores Defendants' incentives to compete in the relevant market;
- c. Enter joint and several judgments against each of the Defendants and in favor of Plaintiff and the proposed Class;
- d. Award Plaintiff and the Class damages (i.e., three times overcharges) in an amount to be determined at trial, plus interest in accordance with law;
- e. Grant Plaintiff and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;
- f. Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees, as provided by law; and

g. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

#### **XIV. JURY DEMAND**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff, on behalf of herself and the proposed Class, demands a trial by jury on all issues so triable.

Dated: September 9, 2020

Respectfully submitted,

By: /s/ Michael M. Buchman

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